

UNITED STATES OF AMERICA

DEPARTMENT OF DEFENSE

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ARMED FORCED EPIDEMIOLOGICAL BOARD

PUBLIC MEETING

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THURSDAY
FEBRUARY 29, 1996

WASHINGTON, D.C.

The Board met at the Walter Reed Army Institute of Research, 14th and Dahlia Streets, N.W., Building 40, Room 3092, at 8:00 a.m., Dr. Lewis H. Kuller, Chairman, presiding.

MEMBERS PRESENT:

Dr. Lewis H. Kuller
Dr. Michael S. Ascher
Dr. Claire V. Broome
Dr. Jack M. Gwaltney, Jr.
Dr. Gregory A. Poland
Dr. Dennis Perotta
Dr. John R. Bagby
Dr. Russell V. Luepker
Dr. Gerald F. Fletcher
Dr. James Chin
Dr. James R. Allen
Dr. Martin Wolfe

STAFF PRESENT:

Colonel Vicky Fogelman, Executive Secretary

BOARD CONSULTANTS PRESENT:

Commander Trueman Sharp
Colonel Frank O'Donnell
Lieutenant Colonel Michael Parkinson
Captain David Trump
Commander David Arday
Colonel Robert Leitch

ALSO PRESENT:

Rear Admiral Web Young
Rear Admiral Noel K. Dysart
Dr. Stephen C. Joseph
Colonel Ernest Takafuji
Colonel Bob McMeekin
Lieutenant Colonel Jeff Gere
Captain Steve Cunnion
Colonel Joel Gaydos
Lieutenant Colonel Robert Defraites
Colonel John Brundage
Captain Bill Berg
Major Jeffrey M. Gambel
Lieutenant Commander Laurel May
Captain Richard Thomas
Colonel Charles Hoke
Colonel George Lewis
Dr. Peter J. Jahrling
Colonel William Bancroft
Colonel Salvatore Cirone
Lieutenant Colonel John Seibert
Dr. John F. Mazzuchi
Colonel Bruce Jones

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COL Vicky Fogelman
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WELCOME

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1 P-R-O-C-E-E-D-I-N-G-S

2 8:09 a.m.

3 DR. KULLER: We can get started I
4 think if you will be seated. I would like to
5 welcome you to the Armed Forces Epidemiology
6 Board meeting. This should be a very interesting
7 and I think rather full meeting of the Board. I
8 am personally delighted to be here and also to be
9 back at Walter Reed, since I started my era in
10 the Armed Forces Epidemiology Board here, and
11 hopefully ending it here. So I am delighted to
12 be here as I have had a lot of good experiences
13 here.

14 I am going to turn the meeting briefly
15 over to Dr. Fogelman for some announcements.

16 COLONEL FOGELMAN: Thank you. I would
17 like to welcome the Board members here. I hope
18 everybody had a good trip, and welcome to Rear
19 Admiral Dysart, who is the Director of Medical
20 Resources, Plans, and Policies and Chief of Naval
21 Operations, Dr. Joseph, Assistant Secretary of
22 Defense for Health Affairs and Director of Health
23 Affairs as well.

24 I have a few administrative
25 announcements. First of all, no food is allowed

1 in the conference room. However, drinks will be
2 allowed if you are sitting at the table. This is
3 not my rule.

4 Lieutenant Hamilton, are you here?
5 Could you step inside just a moment? Lieutenant
6 has asked that those who are driving might see
7 him to give their car make and model and license
8 plate number so that they are not ticketed if you
9 are parking here, please. Other than the flag
10 officers, who can see me and I will make sure
11 that that is done.

12 Telephone access is available in the
13 room next door. We have two telephones and we
14 also have a computer hooked up from which you can
15 send E-mail messages if you wish. If you have an
16 emergency, I have a phone number here. Please
17 call the Headquarters Office, 202-782-3551, and a
18 message will be forwarded. We have rest rooms
19 here in this building. The women's rest rooms
20 are through the corridor and to the left. The
21 men's rest rooms are near the elevator. And
22 there are other rest rooms throughout the
23 building which are marked. If you need copier
24 support, we can have that done in Room 1095 on
25 the first floor. There is also a computer next

1 door as I mentioned. That is really for
2 administrative use, but if you need E-mail, I
3 think it has E-mail capability as well. I will
4 talk a little bit more about lunch after the
5 break.

6 I would like to now introduce Colonel
7 Ernest Takafuji, who is the Director of the
8 Walter Reed Army Institute of Research. He would
9 like to give a few welcoming comments.

10 COLONEL TAKAFUJI: Good morning. Dr.
11 Kuller, members of the Armed Forces
12 Epidemiological Board, Dr. Joseph, Dr. Mazzuchi,
13 Admiral Dysart, it is really a welcoming thing to
14 have you all here because this is where so much
15 activity has already taken place in the past with
16 the Armed Forces Epidemiological Board. I am
17 sure many of you that have had the long
18 association with the Board that I have had have a
19 lot of sentimental feelings about being here at
20 the WRAIR.

21 On behalf of the WRAIR, I want to
22 welcome you all here for this meeting. I also
23 want to make it very clear that this meeting is
24 hopefully one of many meetings that you will have
25 here at the WRAIR. We are, as you can see,

1 nicely set up to be conducive for such meetings
2 and extend that welcome not only to the current
3 board members but to future board members to have
4 your meetings here.

5 The Walter Reed Army's Research is
6 going through a lot of changes right now. One of
7 the biggest changes, as you probably have heard,
8 is that we are in the business of now
9 constructing a new facility out at Forest Glen.
10 So in about a couple of years from now, actually
11 about 1999, we will be moving into a new facility
12 out at Forest Glen. And those of you who have
13 expressed an interest in finding out more about
14 the facility and about our programs, please see
15 me during the break or whatever and I will be
16 glad to bring you up to speed on some of those
17 things that are happening.

18 Without further ado, I would like to,
19 in addition to extending the welcome from me,
20 introduce another person who is from my
21 headquarters, Medical Research and Material
22 Command, and that is Colonel Bob McMeekin, who
23 would like to also welcome you.

24 COLONEL BOB MCMEEKIN: Thank you. Dr.
25 Joseph, Dr. Kuller, distinguished members of the

1 Board and visitors, it is a pleasure to welcome
2 you on behalf of General Zajtchuk, who couldn't
3 be here today. He, as you know, is torn between
4 a lot of different things, and I get the distinct
5 pleasure of filling in when he can't make it.

6 One of our major interests is
7 applications of advanced technology, the various
8 applications in medicine. And as we pursue our
9 thrust into medical surveillance -- worldwide
10 medical surveillance -- one of the things that we
11 will be developing is some video teleconferencing
12 capabilities. So maybe we will be able to see
13 one virtually and we will have a greater
14 participation at some of these meetings.

15 I have watched the development of the
16 Board over the years, and two things have struck
17 me. One is that you bring us to the cutting edge
18 of where we are in epidemiology and infectious
19 diseases. And secondly, you bring us back to
20 reality as we charge off in our research. So I
21 am very pleased to be here to welcome you on
22 behalf of General Zajtchuk. I see you have a
23 full agenda, and without further ado I want to
24 turn it over to Colonel Fogelman.

25 COLONEL FOGELMAN: Yes. Next, I would

1 like to introduce Dr. Stephen Joseph, the
2 Assistant Secretary of Defense for Health
3 Affairs, who has had a distinguished public
4 health career and has
5 certainly --

6 DR. JOSEPH: Why did you put that in
7 the past tense?

8 COLONEL FOGELMAN: Without further
9 ado, I would like to introduce Dr. Joseph.

10 DR. JOSEPH: Do you know something
11 that I don't?

12 COLONEL FOGELMAN: No, sir. No, sir.

13

14 DR. JOSEPH: I am delighted to be here
15 with you. I am going to -- I think I can stay
16 through the afternoon break. It is one of the
17 most pleasurable things that I get to do in a
18 week that is not all pleasurable. And as we
19 talked about at previous meetings, I will try my
20 darnedest to spend as much time at the board
21 meetings as I can. Because I really think we are
22 at not only an upward trajectory to what has been
23 a great history, but also at a kind of turning
24 point for the board.

25 I want to do three things. I want to

1 make a few notes for history buffs, and then I
2 want to mention a couple of things that are
3 currently going on in military medicine that I
4 think are of particular interest to the context
5 of the board. And then I want to talk a little
6 bit about the future of the board. I will try to
7 do all of that in a few minutes.

8 First of all, for the history buffs,
9 being at WRAIR and being at Walter Reed, those of
10 you who are new to this place or haven't been
11 here for a long time, I would urge you to look at
12 this painting over here of William Beaumont and
13 also the painting of Walter Reed, which is on the
14 installation. And those of you who are about as
15 old as I am will remember -- I believe it was
16 Park Davis that had the series of paintings of
17 great moments in medicine that used to hang in
18 every apothecary's window and in your family GP's
19 office when you were a kid. These are the
20 originals of two of those paintings. And a prize
21 goes to the epidemiologist who can remember the
22 name of the French Indian trapper who William
23 Beaumont gastrostomized in that physiological
24 experiment. I think it was St. Cierre, wasn't
25 it?

1 AUDIENCE MEMBER: St. Martin.

2 DR. JOSEPH: St. Martin?

3 AUDIENCE MEMBER: Alexis St. Martin.

4 DR. JOSEPH: The second little
5 historic note -- I am told -- this may be
6 apocryphal, but this room that we are in is
7 sometimes informally called either the war room
8 or the Roosevelt Room. And the legend is that in
9 the months before our entry into World War II,
10 when President Roosevelt wanted to have military
11 meetings out of the eyes of the press and the
12 public, he would come out here to Walter Reed and
13 have cabinet or other strategic meetings in this
14 room. I don't know whether that story is
15 apocryphal or not.

16 DR. ASCHER: Ted Woodward used to come
17 to those. So he remembers.

18 DR. JOSEPH: Well, there you are. I
19 also want -- we have got a couple of people from
20 the press here. I want them to notice how we --
21 take a look around this building and notice how
22 we pamper our biomedical scientists in the
23 military who really contribute in ways I think
24 that the public does not understand to the
25 advance of medicine.

1 Yesterday, Colonel Takafuji and I and
2 perhaps some others in this room were at a
3 ceremony at which Smith-Kline French honored the
4 Army for its work in the development of the Hep A
5 vaccine. That vaccine could not have been
6 brought to market without the military's work in
7 Thailand and in the United States. That is just
8 one story among many.

9 There is a lot going on
10 epidemiologically in military health at the
11 moment. Of course, foremost in everybody's mind
12 is the Bosnia deployment. We have an extremely
13 robust medical support with that deployment, and
14 in particular I think we are doing some things in
15 preventive medicine and surveyance and laying the
16 groundwork for pre-, during-, and post-deployment
17 awareness of health threats and preventive
18 measures to meet them that will set a new
19 standard for us.

20 We are also putting on the ground
21 really the next generation of telemedicine
22 capability in Bosnia, with which we will
23 demonstrate not what we have to date but kind of
24 back and forth single channel capabilities in
25 telemedicine, but really a systemic view where

1 everything is connected to everything else
2 basically, and our ability to move information
3 instead of patients, provide consultation, and
4 build an integral and epidemiologic record will
5 be significantly enhanced.

6 Of the health threats facing us in
7 Bosnia, the two of course that have gotten the
8 most attention are tick-borne encephalitis and
9 hantavirus illness. I want to acknowledge the
10 help of the AFEB in sorting our way through what
11 posture to take with TBE, particularly Mike
12 Ascher. But the board as a whole has been
13 enormously helpful to us in deciding what posture
14 to take. We got a lot of different advice from a
15 lot of different people, and we chose the best
16 course. But I think the focused and timely help
17 from the AFEB was a very important part in that
18 process.

19 Hantavirus, I think, as Colonel
20 Fogelman keeps reminding me, is the main money in
21 Bosnia for us. It is a prevention threat that is
22 widespread and difficult to deal with. I think
23 we are well-positioned to deal with it in so far
24 as preventive measures are available and in so
25 far as therapeutic measures are available. I

1 think that is really the one to watch. But we
2 expect to make the Bosnia deployment an
3 opportunity to demonstrate just how well we do in
4 military medicine.

5 Let me mention two other items briefly
6 that might be of interest to the board. Next
7 Friday, I am going with a group of 12 to the
8 People's Republic of China for what will be the
9 first functional exchange of any type between the
10 two countries in the last 7 or 8 years. And we
11 are taking an extraordinary group of military
12 health specialists to work with the Chinese and
13 talk with the Chinese about possible exchanges in
14 a variety of areas ranging from expertise to
15 occupational health and environmental health
16 issues. We will see how that trip goes, but we
17 are very excited about it, and I think there will
18 be all sorts of interesting issues come back to
19 you professionally and possibly in your capacity
20 as members of the board if, indeed, we are
21 successful on that trip.

22 We are close now to putting out what
23 will be our definitive statement on the Persian
24 Gulf Illnesses and the comprehensive clinical
25 evaluation program. My magnificent colleagues --

1 I can't say enough about the doctors and nurses
2 who have done this work in our hospitals. We now
3 have very sophisticated work-up reports on almost
4 20,000 people, starting from 0 people a year and
5 a half or a little less than two years ago. I
6 think that is extremely good work --
7 extraordinarily good work -- and I think it will
8 be a real contribution to the ongoing literature
9 of epidemiology as well as an important thing for
10 demonstrating credibility of military health
11 services system in taking care of its people.
12 And I expect that you will see that report come
13 out in the next few weeks. I hope you have all
14 seen the IOM report. If you haven't, we need to
15 get copies to the members of the board, which
16 essentially has validated our approach and our
17 work.

18 Let me say just a couple of things
19 about the way I see the current future status of
20 the board. First of all, I don't want to
21 embarrass her, but I think Colonel Fogelman's
22 arrival is a big plus. There are lots of things
23 that you know and probably some things you don't
24 know in terms of the way she has dug into the
25 board's activities and our overall epidemiologic

1 posture already that are most impressive. We
2 have an engine here that I think will help us get
3 where we all want to go in terms of the board's
4 near future.

5 We have a lot of changes coming up in
6 terms of membership of the board, but I want to
7 reiterate, and I hope you will have some time to
8 talk about this as you are here -- I would
9 certainly be happy to talk about it over lunch
10 today and then you can talk about it in your
11 executive sessions tomorrow. I really urge the
12 board to start thinking more strategically and
13 start mapping out where it is that you want to be
14 in terms of the longer run issues and the
15 epidemiologic context for military medicine. I
16 still think you are too focused on short range,
17 small, not in the sense of important, but more
18 limited problems, and we do need your advice on
19 those. Witness the TBE issue there.

20 But I think the real power of an
21 instrument like the board is to get you to a
22 place where you begin to follow over time
23 contextual issues in prevention in epidemiology
24 for the military. We are working on getting the
25 retreat we talked about last time scheduled

1 sometime in this year. And I just urge you to
2 keep molding yourself in that direction. We are
3 looking for ideas from you in terms of topic
4 areas and in terms of methods of approach, and I
5 think you will find us all very receptive to the
6 directions that you come up with. But I think
7 that really is the main challenge.

8 I don't know if I will get another
9 formal chance to thank you, Dr. Kuller, for your
10 leadership of the board in the past, but let me
11 do that while I have a moment here. I suppose we
12 will have a formal opportunity some time, but we
13 are grateful for your leadership and wish you the
14 best in the future. I think I will stop with
15 that, Colonel Fogelman, and let's see how the
16 meeting goes.

17 COLONEL FOGELMAN: I think I will
18 defer to Dr. Kuller now.

19 DR. KULLER: Thank you very much, Dr.
20 Joseph. We are going to move now to some of the
21 issues that were put before the board. Dr.
22 Ascher is going to present the evaluation of the
23 TBE and Hepatitis A vaccine deployment in Bosnia.

24

25 DR. ASCHER: As one that is in the

1 past tense, a few of us are lame ducks. And just
2 before we got a chance to get off, they gave us a
3 very interesting problem to work on.

4 Between meetings -- they didn't wait
5 for the next meeting to have the Bosnian
6 deployment, so we got caught between meetings.
7 But basically we were asked to update Dr. Joseph
8 on the status of our feelings about the tick-
9 borne encephalitis vaccine issue.

10 This was not a new issue. For those
11 of you who don't remember, in 1993, Colonel
12 Takafuji and others presented a great deal of
13 information on the problem with the specific aim
14 to prepare for the eventuality of an exercise
15 like Bosnia. And basically the board
16 recommended, as you see, that the use was going
17 to be recommended most likely and that the
18 measures to proceed to take the product to a
19 status that would allow it to be used, meaning an
20 expanded IND and a modified schedule, were
21 supported full speed ahead.

22 The issues were, however, in the
23 specific context of this deployment, the nuances
24 that had occurred since and very practical things
25 like where is the vaccine and what is it all

1 about. You do have, I believe, the final
2 recommendation. So I am going to have to sort of
3 reverse engineer this. And I am going to dance
4 along the top of some of the issues that came up,
5 and I hope we have a couple of minutes for
6 discussion. I would like to thank everybody in
7 the Disease Control Subcommittee that was either
8 on a telecon or a pre-meeting here on the first
9 of this month, and a group that went to Austria
10 to meet with the individuals from the University
11 of Vienna, from Austrian Surgeon General's
12 Office, the epidemiology people from Yugoslavia,
13 such as they are, and the manufacturer. Several
14 are in the room and they are here to also answer
15 questions if necessary.

16 TBE, as most of you know, is an
17 unusual disease in the Flavivirus family in that
18 it has an interesting clinical picture which
19 presents to us, as one of our comments indicates,
20 a rather interesting management problem in field
21 medicine. The illness has a flu-like prodrome in
22 the classic cases, and then after a -- I won't
23 say a lucid interval -- but after a considerable
24 interval, up to a week, then the onset of
25 neurological problems. And these are about two-

1 thirds aseptic meningitis, about 10 or 15 percent
2 or a little more encephalitis with sensorium
3 changes, and then a small number with paralytic
4 complications. And the paralytic complications
5 are sometimes permanent. So this is an illness
6 that produces basically people that in some cases
7 will be tetraplegic. We saw an example of that.

8 So you have someone in the field with
9 this illness. You send them back to duty and
10 their first manifestation of the second illness
11 is that they have encephalitis. That is a little
12 complicated in terms of figuring out how to take
13 care of that. So that is one twist.

14 The other interesting thing about it
15 is that in another form, a little to the east, is
16 known as Russian spring-summer encephalitis, a
17 little different virus, and here is the reason.
18 It is a very tight epidemiologic curve as you can
19 see over time with the onset of the illness
20 mainly being in April, May, and a peak --
21 sometimes a little second peak, people have
22 talked about, if the weather settles down in the
23 fall. But in general, a fairly tight illness.

24 When we first were asked the question,
25 we figured we had a little while to think about

1 it because we are a little bit ahead of the
2 timing on this.

3 The problem in terms of where disease
4 is and what numbers come out of Europe are the
5 classic problem of reporting bias. We have some
6 numbers, and I am going to leave this up for a
7 couple of minutes, that indicate that the one
8 thing we really don't know is any reliable
9 figures on Bosnia itself. And that has to do
10 with two factors. One is that there is
11 historically not a lot of disease activity ever
12 been reported out of there, but also the
13 disruption of the system, of course, doesn't
14 allow much.

15 But if you look at a couple of the
16 examples from this table, you will see some
17 interesting twists. The couple that I will
18 highlight for you are the northern part of
19 Yugoslavia or the area of Slovenia. You can see
20 that they run 200 to 400 cases a year. And a
21 rather extraordinary finding, which I will show
22 you on a map, that a big change in activity in
23 Latvia after the fall of the wall, if you will,
24 allowed by anecdotes a lot of people into areas
25 of Latvia that were not allowed before and this

1 number of over 1,300 cases we were told was
2 actually over 1,700 cases of tick-borne
3 encephalitis in Latvia. So it suggested that in
4 a situation of environmental disruption, you can
5 have an explosive change. This is only a hint
6 that it can happen. I think those data are
7 reasonably real.

8 You probably would not have thought
9 that Sweden or any of these other areas were
10 areas of activity. Now the one, of course, that
11 is most interesting from our perspective today is
12 Austria. If you go back to the beginning in the
13 late 1970's, you see they had this nagging 400,
14 500, or 600 cases a year. And with the work of
15 the folks at the university, they were able to
16 put together a vaccine program which has
17 basically dropped the incidence to what you see
18 in these residuals years of around 100 to 200
19 cases.

20 Now where the disease is is a bit of a
21 mess. And I will pass this around if anyone
22 wants to see it, and I will show you a poor
23 facsimile of this. This is Europe, as you can
24 see, with Latvia being at the top. And right off
25 the end of the map is the disease activity I

1 documented in Slovenia. And one of the problems
2 we face is there is really nothing any further
3 south in terms of reliable data.

4 So if we put the map of Europe, as I
5 said a poor facsimile on it, this is going to be
6 Bosnia. You can overlay what we had documented
7 on the other map here. And you can see that
8 there is an area centered on Austria, Slovenia,
9 and Hungary that has well-documented high levels
10 of activity and then a blank in the area of
11 Bosnia.

12 Let me make sure you all understand
13 how Yugoslavia is divided because there are a
14 couple of issues. The troops that we are
15 deploying supposedly are coming through Hungary,
16 through a corridor of Croatia, into this region
17 around Tuzla. So this is the area, Bosnia, that
18 we are talking about where most of our forces
19 are.

20 Classically, if you ask the people who
21 keep the older maps, in terms of where tick-borne
22 encephalitis has really been described, you will
23 come up with a statement that Slovenia is a well-
24 known hot spot and Croatia has activity. So you
25 will end up with this kind of distribution. And

1 this was the problem, as I said, that we have a
2 distribution of in Europe extending down to the
3 northern part of Yugoslavia with then sort of an
4 unknown level of activity in the south of that
5 for several reasons.

6 Now one of the bonuses of our trip,
7 and we are not quite sure exactly what to make of
8 it, was a map given to us by the disease control
9 officer from Slovenia. And this indicates that
10 in the areas of Bosnia, which is this ecosystem
11 coming down this general valley with highlands to
12 the south, there is either indirect evidence in
13 terms of antibody surveys or occasional anecdotal
14 cases as derived from the people in Slovenia. So
15 this was the most compelling, and some people say
16 it is not completely reliable, but the most
17 compelling data from the field that suggested
18 there was an extension of the risk down into this
19 region. And there is no reason that it should
20 not be extended down.

21 And the other bit of information which
22 was new to me was the fact that Hungary, which is
23 the corner of Hungary where our troops come
24 through, and this doesn't show very well in terms
25 of the reproduction, is a very well known hot

1 spot. And it is a routine for immunization in
2 this area for at-risk people.

3 Now a word about the vaccine. The
4 vaccine is a classic formal inactivated chick
5 embryo-grown product. It is fairly well worked
6 out. It was developed first in the 1970's and
7 then was remanufactured when some changes were
8 found to improve the -- or decrease the
9 reactogenicity. It is a routine immunization in
10 Austria used now in everybody over the age of 1.

11 And this, although again subject to some bias,
12 is the Austrian counts in terms of incidence of
13 tick-borne encephalitis over the years subsequent
14 to the immunization program. And as you can see,
15 except for the fact that there is no clear
16 classic efficacy trial, it has diminished the
17 case reporting in a significant way.

18 One of the other issues that we had to
19 face is the issue of reactogenicity. Because
20 this was not subject to the same type of trials
21 necessarily -- as I said, no efficacy trial data
22 -- there were concerns that the adverse reaction
23 reporting system that we had access to was not
24 ideal. But we carefully looked at that, and
25 there is a passive reporting system that Austria

1 uses, and they reflected that severe reactions
2 occur at the rate of about 1 in 100,000, and
3 there is no pattern of particular syndromes that
4 occur. So after some lengthy discussion, we did
5 assure ourselves that there was a reasonable
6 safety factor in the use of this vaccine.

7 They have used 40 million doses of the
8 vaccine overall, and I believe 26 million of the
9 newer formulation. They sell about 4 million
10 doses a year and they use about 1.5 million in
11 Austria every year. Correct me if those numbers
12 are wrong. Jeff is here somewhere and some other
13 folks as well.

14 So trying to put all this together,
15 and as I said I am dancing along the top of some
16 of these issues, we came up with the conclusions
17 that you can read in the memo that we
18 acknowledged that this is probably a risk to our
19 troops due to their deployment into the areas of
20 Hungary, Croatia, and Bosnia. Hungary is clearly
21 a risk area. The area of Croatia where they are
22 deploying is clearly a risk area. And Bosnia,
23 again as I mentioned, may be a little less risk
24 area.

25 We estimated order of magnitude at 10

1 to 20 cases in the 20,000 troops for one year.
2 Those are soft numbers, but there is some
3 justification for those numbers.

4 We indicated that there are, in the
5 maps I showed you, classic "stable" environmental
6 foci that have been reported. We were concerned,
7 however, that you could necessarily know where
8 they are at the present, or if you were a
9 commander in the field feel confident that your
10 troops were going to retain a stable relationship
11 with the environment. So we indicated that it
12 was probably not practical to do a really careful
13 local risk assessment, and we could not come up
14 with a means of determining who could or couldn't
15 receive the vaccine. So we sort of concluded
16 that on the basis of that that if you are going
17 to use a vaccine, it would have to be given
18 basically to everybody unless there was a good
19 reason to say there was not risk.

20 In our final recommendation, as you
21 can see, the first recommendation, ahead of
22 anything to say about vaccine, is a very strong
23 emphasis on the use of personal protective
24 measures. And the comment or the language says,
25 "must be implemented by commanders in the field."

1 That was as strong as we could make it, and the
2 emphasis is really there. We felt that both for
3 the purposes of this and things like Congo-Crimea
4 and Lyme disease and everything else that this
5 was a very important factor.

6 We did, however, then recommend that
7 the vaccine be given to all troops deployed to
8 the areas I mentioned and that we better get on
9 it pretty fast because we would like to have the
10 vaccine efficacy in the troops before the tick
11 season starts, which is in a couple of months.
12 We indicated that there is an issue about the use
13 of this vaccine under IND that will require some
14 special considerations and had the services make
15 sure they have the resources necessary to do
16 that. We indicated that rodent control for the
17 purpose of controlling general rodent-associated
18 diseases, particularly hantavirus, would probably
19 be helpful as well, and thought that was worthy
20 of some consideration and emphasis.

21 And then the last thing, which is also
22 one of the indirect references to the other form
23 of tick-borne encephalitis transmission is that
24 you shouldn't eat raw milk in any of this are or
25 any raw milk products. Of course, that also

1 applies to California, but I don't know what the
2 difference is there.

3 Okay, I have danced along the top and
4 I have most of the committee here that
5 participated, and I wonder if there are any
6 questions or comments. I am sort of pressed for
7 time, but I will turn it over to anybody who has
8 any further thoughts. Dr. Joseph, anything?

9 DR. JOSEPH: Well, nothing. We
10 distributed -- we did distribute -- you have in
11 front of you the policy that we eventually sent
12 out. We did the best risk/benefit association
13 that we thought we could garner. Some of the
14 numbers were different from other sources than
15 the ones that Mike has given you. I think there
16 is no question about the issue of personal
17 protective measures, not only for TBE but for
18 other hazards in Bosnia. There is some question,
19 I think, about the degree of risk, both
20 geographic and demographic.

21 We have interfaced, I think, with a
22 kind of classical problem. You have what is in
23 the U.S. an unlicensed vaccine that has not gone
24 through the kind of trials that would be required
25 for licensure in the U.S. It is well established

1 in its use in what is a pretty good public health
2 and medical system in parts of Europe. And then,
3 of course, we had to balance that with the
4 logistic and military issues involved in a rapid
5 immunization campaign for many more than 20,000
6 troops because of rotation of units, et cetera.
7 And you see before you how we arrived at our
8 decision and what it was.

9 Let me just try to be very clear. My
10 view is that the value of a consultant or a
11 consultancy is not measured by whether you take
12 their advice or not, but by the quality of the
13 work and how that informs your eventual decision.

14 I think that is a solid rule in medicine. And
15 the fact that we came out with a different policy
16 in some respects, in major respects, than that
17 that the board and the consultant group
18 recommended, in no way should diminish your sense
19 of how important the advice and what quality of
20 advice it was that we got.

21 This will be an interesting one to
22 watch develop. We have probably in this
23 deployment -- I am told by those with long
24 military medical experience and certainly my own
25 impressions are -- I was out in Bosnia a couple

1 of weeks ago -- Hungary and Bosnia -- we probably
2 have the most direct and strongest line command
3 support for preventive medicine that we have ever
4 had. We have had one so far and expect to have
5 another one in the next couple of weeks, direct
6 messages from the CINC about personal protection
7 and environmental hygiene. And the line
8 commanders up and down the pole are very aware
9 and very cooperative.

10 I know you are going to have a session
11 on this later in the morning, and I am very
12 anxious to hear that. If there ever has been a
13 good chance to better General Slim's record of
14 making sure that the line command enforces
15 preventive medicine measures, I think we have
16 that opportunity now. And beyond that, we will
17 just have to wait and see how it works out.
18 Thank you again, Mike.

19 DR. ASCHER: Would any of the
20 subcommittee have anything to add in terms of
21 correction? Anybody? I thank you all for your
22 work.

23 DR. KULLER: Any questions from
24 anybody else?

25 DR. FLETCHER: Is this a costly

1 vaccine, Dr. Ascher?

2 DR. ASCHER: Jeff, help. Where is he?

3 What was the net bottom-line cost? About \$11.00
4 a dose?

5 COMMANDER GERE: It is \$11.00 a dose.
6 It requires 3 doses over 28 days and then a
7 booster at 9 months for each soldier.

8 DR. ASCHER: It obviously wasn't a
9 problem of supply given that they sell a million
10 a year to give us 60,000. Yes, Dr. Cunnion?

11 CAPTAIN CUNNION: Steve Cunnion. How
12 many -- what percent of the U.N. troops that have
13 been in Bosnia since they went in were
14 vaccinated? And since we provided medical care
15 in Bosnia since the beginning, have there been
16 any diagnosed cases in U.N. troops in Bosnia?

17 DR. ASCHER: Joel, I think the numbers
18 were the Canadians used it for a while and then
19 stopped. The Brits do not and we --

20 COLONEL GAYDOS: The Canadians
21 continue to use it for high risk groups.

22 DR. ASCHER: The Canadians are still -
23 - and we do not know of any reports of diagnosed
24 illness in the U.N. troops, but we are also not
25 clear that they have the capability to make the

1 diagnosis.

2 DR. JOSEPH: I think I can add
3 something more to that, Mike. The Russians
4 probably are coming in with immunized troops in
5 our sector. The British and the French have
6 elected not to use the vaccine. We have had many
7 hundreds of thousands of troops, of course, in
8 southern Germany for many years, many of whom are
9 exposed to field conditions in southern Germany,
10 which is a yellow area on that non-prevalence
11 drug company map. And one of the issues before
12 us was if we were going to use this vaccine now
13 in Bosnia, what do we do about Germany. To the
14 best of my knowledge, there has only been one
15 reported TBE case in American forces in Germany
16 over the last many years with many hundreds of
17 thousands of man-years of exposure.

18 DR. ASCHER: I believe we do have now,
19 at present, in the field the lab capability to
20 make the diagnosis, which the U.N. did not.

21 DR. KULLER: Thank you very much. I
22 am sure this will rise up again in board
23 discussions over the next months and years.
24 Anybody else?

25 I think the next -- we are going to

1 move on, I think, to Dr. Fletcher and Colonel
2 Parkinson talking about clinical preventive
3 services.

4 DR. JOSEPH: Was Mike going to say a
5 word about Hep-A?

6 DR. KULLER: Oh, Hep-A. Were you
7 going to talk about Hep-A, Mike? Could we just
8 have a brief -- I missed the boat. Sorry. Thank
9 you.

10 DR. ASCHER: Before the -- yes, the
11 question that came to the board was actually a
12 two-part question, which was the issue of a final
13 recommendation on Hepatitis A. And through a
14 teleconference, we decided that we would reaffirm
15 the previous position that the Hepatitis A
16 vaccine was the method of choice of prevention
17 and should be used routinely in all troops prior
18 to this deployment. And I believe that has gone
19 forward.

20 DR. KULLER: Okay. Clinical
21 preventive services for men.

22 DR. FLETCHER: Thank you, Dr. Kuller
23 and members of the board. As you know, the three
24 subcommittees or committees or committees of the
25 AFEB are quality control, disease control, and

1 last but not least health maintenance. And I
2 have been asked as chair of that committee to
3 address a memo from Dr. Joseph that is in your
4 handout regarding his request for us to provide
5 assistance in determining the appropriate
6 clinical preventive services for men that should
7 be provided as a routine benefit in the military
8 health services system.

9 Our plan of presentation this morning
10 is for me to give a little background of
11 reasoning for this and go into the
12 recommendations that I have put together based on
13 some of the data that we have here on the routine
14 recommendations. Dr. Michael Parkinson will then
15 go into some of the more controversial areas. I
16 think his expertise working with my experience
17 and my review of this will hopefully give you a
18 platform of issues to talk about. We have some
19 recommendations in front of you and we can
20 address these as you would like it henceforth.

21 So if we can start with the slides,
22 please. The first slide is Dr. Joseph going to
23 China. Maybe he could check this out.
24 Anecdotally, many years ago the Yellow Emperor's
25 Classic of Internal Medicine, said to have been

1 composed about 2500 B.C. and written down in the
2 second century, "The role of the physician was
3 not to cure disease. Indeed, such a task would
4 be undertaken only by a poor physician, one who
5 did not know his business well enough to have
6 avoided the problem in the first place." And the
7 emperor customarily paid his physician a regular
8 retainer and stopped paying when he stopped
9 feeling well. And the sages and the wise men of
10 that time did not treat those who were already
11 ill. They instructed those who were not yet ill.

12 So the history of prevention goes back quite
13 some ways prior to certainly our current way of
14 medical care and practice.

15 A little more current, Moments in
16 Medicine, "No longer is our highest aim to cure
17 disease but to prevent it.", by William Osler.
18 In more detail, he taught his students under the
19 plain trees outside in the olden time, as Osler
20 followed sort of Hippocrates's ways of olden
21 times. Osler brought on thoughts that actually
22 Hippocrates had had. So William Osler
23 dramatically changed in his relationship, as
24 first professor of medicine at Hopkins, the
25 teacher/medical student relationship, bringing

1 students to the hospital ward. His teaching
2 method spread through the United States, and he
3 called the modern period the age of preventive
4 medicine. This is certainly within our
5 reasonable era and stresses the critical
6 importance of cutting disease off before it ever
7 gets started.

8 This slide represents more currently
9 some data from 1990 from the Department of Health
10 and Human Services from the Carter Center in
11 Atlanta. Just an interesting way to look at
12 prevention in general, at the 10 leading medical
13 causes of death -- now we are trying not to, of
14 course, deal just with death but morbidity prior
15 to that. But the ultimate endpoint, I think,
16 that we will be dealing with, the Armed Forces of
17 the 1.7 million active, I believe, and the total
18 of about 2.5 million with reserves, a very
19 mottled population. We could deal with looking
20 at the long-term effects of 10 medical causes of
21 death. As you can see, heart disease, of course,
22 cancer, cerebrovascular disease -- we are going
23 on down to things that our military personnel are
24 involved with
25 -- accidents and pneumonia influenza, suicide,

1 diabetes.

2 And looking at the right, the
3 lifestyle factors that lead to about half of
4 them. Number one on the list, as you can see,
5 400,000 deaths thought to be related to tobacco
6 on a yearly basis. Diet or sedentary lifestyle
7 are 300,000 combined. Alcohol itself 100,000.
8 You can just go right on down the list to see
9 things that we can prevent. Looking at the total
10 actually on the bottom, just a way to look at
11 this through statistical means, about 1 million
12 deaths we can avoid by prevention.

13 I think this is a very important role
14 for us to play in the military dealing with
15 things that we can prevent. I showed you some of
16 this a few months ago, and just briefly the Koop
17 National Service Award, looking at America's best
18 wellness programs and companies. Of course, you
19 can't compare the military to companies directly,
20 but there are ways we can, I think, look at the
21 things we may do to -- like jogging for dollar
22 and like Quaker grants or bonuses of certain
23 amounts for families who can be stimulated to
24 shun smoking and to exercise and wear seat belts,
25 some basic things to prevent injury. And making

1 employees safe and healthy like Steelcase or seat
2 belt use to cholesterol and other types of
3 prevention really netting in dollars that are
4 saved and a healthier work force.

5 Dow's Backs the Action Program
6 encourages exercise, dieting, and ergonomics.
7 They have decreased on-the-job sprains and
8 strains up to 90 percent, which are
9 musculoskeletal but which really impair people,
10 and I am sure we see a lot of that in the
11 military, and impair people's performance.
12 Remembering my days in sick-call with the
13 Marines, a tremendous problem.

14 An apostle of prevention is Dupont, a
15 major company also, and you can read this. The
16 flu shots and things that they believe are
17 valuable enough to budget a million dollars a
18 year -- 40 million a year.

19 Now studies by Johnson and Johnson at
20 the University of Michigan -- as you remember, we
21 talked some months back. Quitting smoking
22 probably a savings of \$1,010.00 per year, the
23 average cost of a smoker. Starting to exercise
24 saves an individual \$260.00 a year -- lowering
25 cholesterol and losing weight. So there are ways

1 to look at this from the standpoint of monetary
2 value as well.

3 And you can look at it, as some of our
4 physicians say as sort of a cartoon -- providing
5 you eat sensibly, stay off the beer, cigarettes,
6 and the whiskey, and don't take any strenuous
7 exercise and keep away from women, you could live
8 for another 20 minutes, and there have been data
9 as to what it does to lower your cholesterol.
10 How many more days of life or days of life free
11 from illness? So I think this is just a little
12 background.

13 Our question has been to the
14 appropriate clinical preventive services that
15 should be provided as a routine benefit in the
16 military health services system. And for
17 consideration by you at this meeting and we can,
18 of course, make this flexible and informal after
19 we present this.

20 Now the U.S. Preventive Services task
21 force I think was a very integral group that came
22 up with a lot of recommendations. Dr. Parkinson
23 will probably get into this some more also. The
24 background was based on the Canadian task force
25 model. The first report was in 1989, updated in

1 1995. Evaluation of 70 topics and conditions.
2 Looking at general and high-risk group period
3 health exam recommendations. This was the basis
4 for many basic benefit packages.

5 Now the methodology of the group was
6 targeting the leading causes of morbidity and
7 mortality, some of the things we mentioned
8 previously. Standardized epidemiologically-based
9 literature review and grading of evidence --
10 recommendations based on the evidence --
11 evidence-based, as many publications are now
12 coming out. Review by experts, organizations,
13 specialists, and scientists in the United States,
14 Europe, Australia, and Canada.

15 Major criteria effectiveness
16 evaluation. The test must -- the routine tests
17 that we recommend must detect a target condition
18 earlier than without screening with sufficient
19 accuracy. Screening and treatment for early
20 disease should decrease disease-specific
21 morbidity and mortality compared to treatment
22 when the patient presents already with the
23 disease -- with symptoms and signs of the
24 problem. So it must make that qualification.

25 Now there are a number of authorities

1 we look to for these recommendations. I spoke to
2 some people who had been involved in military
3 medical care in various capacities. I reviewed
4 the literature. We have the generalists group
5 here listed, the American Academy of Family
6 Practice, the Canadian Task Force, the American
7 Cancer Society, the American College of
8 Physicians, which in general is not at times as
9 liberal with recommendations as the American
10 Heart Association, from the standard particularly
11 of cholesterol control that we are not in
12 agreement with, and the Society of Internal
13 Medicine.

14 Now the specialist groups, of course
15 including the American Heart, as I mentioned, and
16 including also the NIH, NCI, and NHLBI, the
17 American College of Cardiology, which is a more
18 conservative group of mainly cardiologists who
19 are becoming more and more prevention oriented
20 from the standpoint of cardiovascular, the
21 American Urological Association, which Mike will
22 probably get more into with regard to PSA,
23 because I know that is a particular concern, and
24 the American Gastroenterological Association.

25 Now one reference that I have that is

1 in your handout and I thought was quite valuable
2 was by SOX in the preventive health services in
3 adults, sort of an editorial type of consensus
4 paper, I guess you might say, in the New England
5 Journal in 1994. It goes into various and sundry
6 references looking at some of the task forces I
7 mentioned and many of the other sources and
8 classifying in a table routine or specific. And
9 I think we are looking more at routine and a lot
10 of this was lifted out of those recommendations.

11 There will be others that we will be mentioned
12 subsequently by Dr. Parkinson.

13 Now what we have done is classify what
14 we do in three components: screening;
15 counseling; and lastly, immunization/treatment.
16 And what we are recommending routinely, again to
17 be modified with your discussion or whatever,
18 these are just to get these things on the table.

19 Routinely height and weight, blood pressure,
20 both systolic and diastolic, murmurs of the
21 heart, especially diastolic murmurs. Because it
22 is our experience in cardiovascular that these
23 diastolic murmurs can be harbingers of
24 endocrinitis and other problems, more so than
25 systolic, but if one can auscultate as helpful.

1 A skin exam for various things has been found to
2 be routinely beneficial. A breast exam greater
3 than 40 years of age. This is routine. Blood
4 lipids and cholesterol. And we need to decide is
5 it just the total cholesterol, the LDL, probably
6 not routinely the HCL, but that is for concern.
7 Complete blood count, urinalysis, and many have
8 felt a blood glucose is very important,
9 particularly because of the enormous prevalence
10 of diabetes and how we are detecting that early
11 and how we can manage that properly to avoid end-
12 organ complications.

13 Now the questions in screening that we
14 will discuss. When do you do the occult fecal
15 blood? Greater than 50 years of age maybe?
16 Maybe earlier. Again, the big item, prostatic
17 specific antigen. Some have recommended greater
18 than 50 only, but I think this is for discussion.

19 And hearing and probably visual is another area
20 of screening questions that we need to discuss.

21 Counseling in general, fairly much
22 agreement on this, about tobacco, alcohol, and
23 substance abuse, nutrition, physical activity and
24 exercise, injury prevention, sexual behavior. I
25 have added domestic violence because of the

1 recent interest and importance of this in all of
2 our society -- in patients I have seen in my
3 practice in many areas -- the aging, the
4 adolescents, adults. And lastly, dental care.

5 Immunization and treatment of tetanus,
6 diphtheria, pneumococcal, greater than 65 years
7 of age and influenza greater than 65. There is
8 some question about these, and I think these are
9 in the group that need to be further discussed.

10 I will stop at this point. And if
11 there are comments, we can. But I would rather
12 move on to Dr. Parkinson, who is going to go into
13 some of the more controversial areas. And, Dr.
14 Kuller, we can pause for questions or comments,
15 or go right into Mike.

16 DR. KULLER: Why don't you have Mike
17 present, and then we will take questions.

18 DR. FLETCHER: I think that is best.

19 COMMANDER PARKINSON: Thank you, Dr.
20 Fletcher. It is interesting -- this microphone,
21 you feel like you are in Trump's casino or
22 something and you can walk around. It is
23 interesting you brought up Dr. Osler, because
24 also at the same time, as you know, there was Dr.
25 Welch, who was the first dean of the School of

1 Public Health at Hopkins. And I recently had the
2 chance to review the proceedings at the
3 Rockefeller Foundation in 1913 through 1916,
4 which established schools of public health. And
5 the issue of clinical preventive services is
6 right at that interface of how you try to combine
7 a population-based perspective on an individually
8 delivered clinical preventive service. And as we
9 get into this discussion, what you will see is
10 the tension becomes what is good for a population
11 or what is good for a minimal benefits package
12 versus what is good for Mike Parkinson or Jerry
13 Fletcher in their perspective and the perspective
14 of the physician taking care of them.

15 Ironically, that perspective, at least
16 in 1913 by people like Abe Flexner, basically
17 they felt that that perspective of population and
18 particularly getting physicians out of the mode
19 of thinking in terms of one-on-one patient care
20 was not something we could do in a medical
21 school. And, therefore, the decision was made by
22 that august group to set up a separate structure
23 called a School of Public Health, which was then
24 funded some 22 schools over the next 50 years by
25 the Rockefeller Foundation.

1 But, indeed, it is that tension that
2 runs through this entire presentation. What I
3 would like to do is very briefly summarize some
4 of the broad areas of consensus. Because there
5 tends to be a sentiment that because we don't
6 agree on this preventive service or that
7 preventive service that there is little or no
8 consensus about what you should do. And, of
9 course, nothing could be really further from the
10 truth.

11 I want to get a little bit more into
12 the exact evidence that was used and why the
13 preventive services task force is really a unique
14 resource in this area relative to some of the
15 other authorities that make recommendations. And
16 that is that the quality of evidence was
17 specifically graded for all those 70 target
18 conditions along the following lines. Grade 1
19 was that there was at least one properly
20 randomized control trial to address whether or
21 not screening for that condition decreased
22 morbidity and mortality. II-1 was that there was
23 at least one well-designed control trial without
24 randomization. II-2 was well-designed cohort or
25 case-control study. And finally, the lowest

1 level of evidence, which is not to say it is not
2 important but certainly traditionally this has
3 been the highest level of evidence coming out of
4 institutes in terms of what does the chairman of
5 X department at the top 10 medical schools in the
6 country think, that is the opinions of respected
7 authorities and expert panels, was actually given
8 relative to the other levels of data the lowest
9 level of evidence.

10 Now that doesn't mean that they
11 discarded it completely. It certainly was
12 important. But the notion here was by doing this
13 they also defined a research agenda where we just
14 don't have good data for some key areas that we
15 need to have done.

16 Taking that evidence, then, how did
17 they basically go to the strength of the
18 recommendations. As Dr. Fletcher said the
19 recommendations were based on the quality of the
20 evidence. And basically, if you had high quality
21 evidence basically you would get an a) good
22 evidence for including that screening test,
23 immunization, or counseling intervention in a
24 periodic health examination; b) fair evidence for
25 it, again moving down that evidence hierarchy; c)

1 insufficient evidence for or against the
2 recommendation to include it, in other words
3 there is just not enough out there; d) there is
4 fair evidence against -- there is fair evidence
5 that by doing this condition you do not lead to
6 decreased morbidity and mortality, and you
7 certainly should not include it -- or you should
8 think of not including it specifically because
9 the evidence is leaning more that other way; and
10 e) there is good evidence against including it,
11 in other words something definitely you don't
12 want to do.

13 Now once all is said and done -- this
14 is a little bit busy slide -- but I just wanted
15 to show you. We are not going to go down here.
16 But many of the areas that Dr. Fletcher covered,
17 with the exception of some of the laboratory
18 screening tests, quite frankly the glucose,
19 routine CBC, and U/A, are less well covered. But
20 what you can see here in the very dark bars, and
21 we are looking at screening tests, examinations,
22 and immunizations, and counseling or health
23 guidance, what you can see in the dark bars is
24 that those are those screening tests which are
25 recommended by many or all -- recommended by all

1 major authorities. So all those large
2 generalists groups that do make recommendations
3 in areas along with preventive services task
4 force, Canada task force, et cetera.

5 And all I want to leave you with is
6 the notion that the black bars are quite
7 prominent across wide areas of consensus. So
8 that far from being differing areas of what
9 should be included for screening, counseling, and
10 immunization, there is a broad amount of
11 consensus. When we start getting differences,
12 and that is what is highlighted in Dr. Joseph's
13 question to the board, is in these very highly
14 visible, high controversial, highly
15 epidemiologically and economically charged issues
16 like PSA testing, fecal occult blood, and
17 sigmoidoscopy, for example, for colon cancer.
18 And, indeed, you see here that you get into PSA
19 testing, you get into sigmoidoscopy, urinalysis
20 periodically, exams for cancer in terms of what
21 is a clinical component of what you lay your
22 hands on or listen to when you go to see a
23 patient. But overall, there is tremendous
24 consensus. And I think that is an important
25 take-home message.

1 I want to concentrate instead on some
2 of the controversial areas. Some of these are
3 very controversial and some are less
4 controversial. And very quickly blitz through
5 with you some of these areas and some of the
6 recommendations, both the evidence and the
7 recommendation made by the task force in these
8 following areas: coronary heart disease, colon,
9 lung, thyroid, glaucoma, counseling
10 interventions, and spend some time on prostate
11 cancer screening -- because it is the squeakiest
12 wheel right now. The question is, should it get
13 more grease. I don't know.

14 Coronary heart disease. Routine x-
15 rays, HDL cholesterol and triglycerides all
16 basically get a recommendation of C, meaning that
17 there is insufficient evidence for or against to
18 routinely include these in a periodic medical
19 examination. In the area of colon cancer, direct
20 rectal examination, both because you can only
21 measure, if you are lucky, maybe a couple inches
22 of that area that you are trying to screen with
23 DRE, digital rectal exam gets a level of 3, again
24 insufficient for or against in a C, but there is
25 good evidence now, and this is a new

1 recommendation since the original 1995 task force
2 review of this issue, for fecal occult blood
3 testing in greater than 50 on an annual basis and
4 sigmoidoscopy periodically gets also a level B,
5 that there is fair evidence for including that in
6 a periodic exam, and both of them are recommended
7 to be done together.

8 Periodicity is very difficult with any
9 screening recommendations. The reason is, there
10 is very, very good studies on whether or not
11 tests should be included in aggregate, but very,
12 very few studies that have randomization or
13 control around strictly the issue of periodicity.

14 So, again, as you say, whether or not the tests
15 should be included, that is decision node one,
16 and then secondarily the periodicity is something
17 that oftentimes you are led down into grade level
18 3 -- well, I think it should be every 3 years and
19 I think it should be every 5 years. Certainly,
20 it shows that it should be included in a periodic
21 health exam.

22 What about lung cancer. I know that
23 we still have individuals -- I am not speaking
24 just for the Air Force -- we still have people
25 out there mistakenly taking routine chest x-rays

1 thinking that they can do something in the
2 occupational health side of the world to detect
3 lung cancers or some other types, for lung cancer
4 specifically. And there is evidence against
5 including that routinely as a routine
6 administration of thyroid function tests.

7 Glaucoma and tonometry basically
8 despite the evidence there, it is routinely done
9 by many, many people. The task force says there
10 is basically insufficient evidence for or against
11 to routinely do glaucoma testing.

12 Now I just want to review, as we get
13 into the PSA issue, again this slide which Dr.
14 Fletcher quickly went over. Screening must meet
15 the following conditions, and that is that it
16 must detect it earlier than without screening,
17 and number two, that once you've detected the
18 condition that intervening at that stage has a
19 different outcome in terms of morbidity and
20 mortality than if a person just normally
21 presented to you at the clinic.

22 What are the tests that are available
23 for prostate cancer screening. There is
24 basically three, digital rectal examination,
25 prostate specific antigen, and transrectal

1 urethral ultrasound, and all three have been
2 systematically reviewed by a number of the
3 authorities that we looked at up here.

4 Let me just talk one minute. Of
5 course, DRE you've got the problem of literally
6 and figuratively reaching an area -- as being
7 defined as abnormal or positive. Transrectal
8 ultrasound, likewise, there are some concerns
9 about this test in terms of the cost and
10 discomfort of having that done widely as a
11 screening test. Nevertheless, let's look at what
12 the task force says. Basically, these
13 recommendations now are about 6 months old. For
14 DRE, PSA, and for TRUS, all three of those they
15 recommend level D, that have is, fair evidence
16 from the data against including any of these
17 tests in routine screening of men for prostate
18 cancer.

19 Let's get in a little bit and look at
20 why that is the case. Again, going against those
21 macro-requirements that they talk about. Of
22 course, this is where the controversy comes. As
23 Dr. Joseph notes in his letter, as the American
24 Cancer Society and American Urological
25 Association, as they have in other areas related

1 to cancer screening, basically they call for an
2 annual rectal examination greater than 40 and an
3 annual PSA greater than 50 among African American
4 males in which there is evidence that there are
5 more aggressive forms of prostate cancer greater
6 than 40.

7 Now keep in mind that the American
8 College of Physicians and AAFP are currently
9 reviewing this whole area. Again, it is very
10 lively. I might also refer you, as a matter of
11 fact, to this which literally arrived on my desk
12 yesterday. AHCPR's review this month of four
13 major studies in the whole area of PSA, DRE, and
14 informed decision making as it relates to
15 treatment for prostate cancer. So not only is
16 there controversy at the screening end but also
17 at the treatment end, and we will show you why.

18 By the way, the annual DRE or the DRE
19 for the purpose of detecting colon cancer is
20 recommended above the age of 50.

21 In a very good review article of this
22 that was published approximately two months ago
23 in the New England Journal of Medicine by Dr.
24 Steve Woolf, reviewed all of the issues in the
25 context of an epidemiologic screening test. I

1 will briefly go into these. Is prostate cancer
2 "serious" in terms of the burden of suffering
3 suffered by obviously both the patient and by the
4 population to which you might apply screening
5 tests? Is the screening accurate? Sensitivity,
6 specificity, positive predictive value,
7 reliability, validity? Does early detection
8 improve the outcome? Is screening or treatment
9 harmful? What are the downstream effects of what
10 we are talking about by administering this test
11 on an individual population basis? And finally,
12 are we doing more harm than good?

13 The problem with prostate cancer is
14 that many people die with rather than of prostate
15 cancer. It is a very, very common, prevalent
16 disease. There is recently some autopsy studies,
17 and I see some of our colleagues here from AFIP,
18 that suggested that even among men the age of 30
19 that basically you can detect 10 or 15 percent
20 with microfoci of prostate cancer. And that
21 increases with age. We do know that there is a
22 difference of 10-year survival rates, like many
23 tumors, based on the degree of metastasis, as
24 basically outlined here. But 30 percent of men
25 over the age of 50 have evidence of histologic

1 disease, and if you extrapolate this nationally,
2 that means over 9 million men in the United
3 States basically have some evidence of this over
4 the age of 50.

5 Most cancer, however, as I said, is
6 not clinically important in the sense that it is
7 -- and I just forget the number off the top of my
8 head of -- what about 40,000 deaths -- I think it
9 is the 12th or 13th leading cause of death among
10 men. But at any rate, what I wanted to say is
11 that the reason, of course, that this is getting
12 in the press and getting on the medical agenda is
13 really twofold. One is that new technology, as
14 in many cases, has outstripped our ability to
15 deal with it. And number 2, highly visible and
16 very, very vocal individuals -- and Bob Dole
17 basically writes editorials in the Washington
18 Post about why it is important for you to go out
19 and get your PSA test and the Mayor of the
20 District of Washington has a very widely
21 publicized case of prostate cancer hospitalized
22 at Hopkins -- it drives the issue. And we have
23 to be able to address it, I think, scientifically
24 as well as sensitively and compassionately as
25 physicians.

1 Is the test accurate? Well, the
2 positive predictive value of this test, and again
3 that is the individuals who test positive above
4 4, what is the proportion of those individuals
5 who actually have prostate cancer. It is, at
6 best, 28 to 35 percent. Now what you can do is
7 you can combine that. If you combine that with a
8 positive clinical digital rectal examination you
9 can get the positive predictive value up to about
10 49 percent. However, even in populations where
11 you do that, you will find approximately 20
12 percent of that population, combining those two
13 tests to increase your positive predictive value
14 -- 20 percent of that population will go on to
15 needle biopsies. And we will talk about a 20
16 percent needle biopsy rate among a -- with a
17 positive predictive value at that on a population
18 basis is very large.

19 The bottom line is two thirds of those
20 individuals with a PSA greater than 4 are false
21 positive, and basically neither the PSA nor the
22 histologic findings predict with certainty the
23 likelihood of progression. So, again, the issue
24 of clinically important raises its head.

25 Once we detect that cancer, can we

1 improve the outcome? The bottom line is we don't
2 have direct evidence that treatment improves
3 outcome. And one of the studies that has just
4 been reviewed in this AHCPR document suggests
5 that even at the age of 65 that operating even
6 that early in life that there is no difference in
7 morbidity and mortality in people operated on
8 versus those not operated on. There are a few
9 well-performed control tiles. Lead time and
10 length bias are rampant in this particular
11 cancer. And basically we are down to this level
12 of degree. Now we will have studies in about
13 another 8 to 10 years that will definitively
14 answer this question.

15 It is not by chance that Dr. Jack
16 Wennberg and others at Dartmouth have selected
17 this condition to talk about informed decision
18 making at the bedside as it relates to physicians
19 and patients. Redefining the whole
20 physician/patient paradigm around this particular
21 condition because of the downstream effects of
22 not only the screening but also of the adverse
23 effects of treatment.

24 Early stage cancers bottom line may
25 have very good outcomes without treatment at all.

1 The downstream effects for that two thirds false
2 positive that we are now identifying with this
3 test saying that you may have cancer or indeed
4 you do have cancer are the following. At the
5 very least, we have got to repeat the PSA. We
6 are talking about ultrasound tests that we
7 mentioned before, which is again something you
8 could add to try to increase the positive
9 predictive value. The needle biopsy, which is
10 very, very -- it is not very sensitive because of
11 course you are basically biopsying anything from
12 a walnut to an enlarged golf ball and hoping that
13 you hit one of the microfoci, and even then if
14 you find one, you may be better off if you missed
15 it in the first place. But at any rate -- but
16 certainly the psychological concern of having
17 this test positive and what we do about it.

18 Side effects are impotence,
19 incontinence, and rarely death with a mortality
20 reported as 0.2 to 2 percent. It can be lower in
21 specialized centers and certainly lower in men
22 less than the age of 65 who do not have co-morbid
23 conditions.

24 The bottom line is, and the task force
25 grappled with this, is the screening. In toto,

1 when you look at it across the board, does it do
2 more harm than good. There is a lot of
3 scientific uncertainty about benefit or harm.
4 But certainly we do know that with the prevalence
5 of this condition, the widespread prevalence
6 among men generally, that annually if we were to
7 screen nationally men greater than the age of 50,
8 it would be 12 to 28 billion annually associated
9 not only with the screening PSA but with the
10 necessary and obligatory 20 percent of
11 individuals who then go on to get needle biopsies
12 who then go on to get ultrasounds and who then
13 may go on to TURPS or radical prostatectomies
14 and/or radiation therapy.

15 The other thing I would add to you --
16 this is more Mike Parkinson than the U.S.
17 Preventive Services task force -- but there is
18 certainly a clinical opportunity cost. If I am
19 spending a lot of time chasing down a screening
20 test and even counseling patients for tests that
21 may not have been wisely offered in the sense of
22 like -- you know, in terms of other things I
23 could be doing to address those 10 leading real
24 causes of death. I mean, if I can double smoking
25 cessation rates, a background rate of 5 percent

1 to 10 percent, with a 5-minute structured
2 intervention for the leading cause of death and I
3 am spending hours chasing down a PSA level, there
4 is a true prevention opportunity cost on not only
5 the individual but the population. And once you
6 codify something as a minimal benefit, it becomes
7 a contract between the provider and the patient.
8 And to that degree, it becomes a much bigger
9 issue than whether or not the person's PSA value
10 is greater or less than 4.

11 With that in mind, about a year ago we
12 in the Air Force basically said we have got an
13 epidemic going on of PSA testing. One of the
14 things that we are trying to do is basically get
15 our preventive medicine folks to think about
16 doing outbreaks in health care the way they would
17 do an outbreak in measles, and to look at the
18 factors that predict how we can control these
19 things. And what we basically found, looking at
20 our epidemiology laboratory, which is not a well-
21 designed control trial by any means -- but what
22 we basically said is that we have a central
23 laboratory at Brooks Air Force Base in San
24 Antonio, and we do basically overnight Fed
25 Express laboratory testing for a variety of

1 conditions for all our MTF's in CONUS. And what
2 we did was from 1991 to 1993, we just said well
3 what has been the increase? And basically we saw
4 about a 360 percent increase in a two-year period
5 of time. That is against a background of an 80
6 percent increase in the number of tests that the
7 Epi lab did for other conditions. So a four-fold
8 increase greater than background as it relates to
9 PSA.

10 And interestingly, when we started to
11 look at who these were being ordered on, 5,000
12 were on men over the age of 75, who under
13 anybody's idea of care probably would not be a
14 candidate for radical prostatectomy given that
15 many guidelines are now suggesting if you have
16 less than 10 years average survival that because
17 of the natural history of this disease that the
18 morbidity and mortality associated with the
19 radiation therapy and the radical prostatectomy
20 are greater than the likelihood of dying from
21 some other effect. 6,000 were performed on men
22 under the age of 50, 800 under 40, and 129 under
23 30. So we are getting PSA creep into ages and
24 populations here -- and again this is just a
25 snapshot of what is happening in our Air Force

1 health care system.

2 Now, of course, with all those tests,
3 as I just showed you, with a positive predictive
4 value of somewhere around 20 to 30 percent if it
5 is not combined with a DRE to get it up around 48
6 percent, what are the downstream costs associated
7 with those tests that are all falling into these
8 areas. We have no way of measuring that or
9 linking that right now, but certainly there is
10 evidence to suggest that anywhere from 20 to 40
11 percent in the civilian sector may go on to get
12 needle biopsies, ultrasounds, and the concern
13 that goes along with it.

14 Interestingly, the radical
15 prostatectomy rates during this time tripled.
16 Now nationally, from 1984 until about 1994, as
17 this test came on line, there has been a four-
18 fold increase in radical prostatectomies in men
19 over the age of 75. Again, this is an area that
20 even the urologists would suggest that this is
21 not a high -- you know, many would say this is
22 not a high yield area to be doing radical
23 prostatectomies on men who are 75 or 80 years
24 old, but yet there has been a four-fold increase
25 in the rate of that as this test came on line.

1 Good for us, basically, was some --
2 because basically we work very closely with our
3 folks in the Urology Department at Wilford Hall -
4 - is that our rate of men above the age of 75 is
5 very stable at 1.5 percent. So this has been an
6 area that we have been looking at very
7 specifically as a system trying to make sure that
8 our front-end screening does not drive practice
9 patterns downstream. But there is much more we
10 need to do on it.

11 The question is nationally certainly
12 more testing has led to more surgery. Has it
13 improved outcomes? And that is the big question.
14 What in the civilian sector is going on with
15 respect to this test. Many of you may have heard
16 of Group Health Puget Sound and Dr. Ed Wagner and
17 others, which really is one of the more
18 progressive, forward-thinking, and I would
19 compassionate HMOs in terms of dealing with
20 patient concerns and also scientific issues. And
21 what they did, just as we did, is they documented
22 over-utilization of the PSA test as this came on
23 line by clinicians, largely in response to
24 patient demand. I mean physicians generally
25 don't go out and say I want to do this test

1 unless they are asked for it.

2 They pulled together a panel of their
3 own people in-house and basically said the
4 downstream health and cost effects were just not
5 warranted, and they established a clinical
6 practice guideline that requires the patient to
7 read and sign an informed consent piece of paper
8 before this test is administered advising him
9 that if you get this test and if you are in this
10 age range, it is likely that you are going to
11 have a false positive result. Can you live with
12 that result realizing that you may want to pursue
13 it with this test which has this complication,
14 this test which has that cost, and this test, et
15 cetera. Basically they are monitoring use and
16 requiring informed consent.

17 What the task force has concluded is
18 that if you offer this test, it should only be in
19 men over the age of 50 with informed consent and
20 in association with a DRE to increase the
21 positive predictive value. But overall, the
22 recommendation is a D.

23 The other final piece of information
24 is that certainly this issue has been cooking
25 within health affairs and within the services for

1 a number of years as we have put together our HMO
2 package, if you will, Tricare Prime. And without
3 going into all the specifics, this currently is
4 the package that we have for adult males. Blood
5 pressure, height, weight, cholesterol measuring,
6 prostate, with a prostate basically specifying a
7 DRE in men over the age of 40, for colon cancer
8 we are very progressive here with a DRE greater
9 than 40, the task force says 50, with a fecal
10 occult blood and sigmoidoscopy greater than 50,
11 and we include periodic sigmoidoscopy once every
12 3 to 5 years -- a flexible sig rather -- I'm
13 sorry, a flexible sig or sigmoidoscopy. A vision
14 and hearing for high risk, not routinely, and
15 counseling and adult immunization similar to
16 along the lines that Dr. Fletcher covered in
17 those broad areas of consensus.

18 The conclusions page is essentially
19 blank for a reason. And I think that what we
20 talked about when Dr. Fletcher and I talked about
21 this was that there are really two groups of
22 concerns. One is what we offer as a minimal
23 benefit for adult males. My personal view is
24 that we are about 85 or 90 percent on target and
25 I don't see any major changes with some squashing

1 around of some age groups. I think that the
2 science of PSA testing specifically and the whole
3 evidence related to its efficacy, there is better
4 evidence against including it than including it
5 in a routine periodic examination.

6 The second issue is what we do vis a
7 vis special occupational groups and military
8 members. Tricare Prime is a package, of course,
9 we offer for those who enroll in our plan, which
10 is essentially all active duty military members,
11 but there are additional physical examination
12 requirements that we basically have for people on
13 flying status or the Navy would have for people
14 assigned to ships or things like that which are
15 really not addressed, I don't believe, in Dr.
16 Joseph's question.

17 But beyond those broad considerations,
18 we thought that we would then turn it back to Dr.
19 Fletcher for further discussion and comment.

20 DR. FLETCHER: Thank you, Mike. Any
21 comments or questions? I guess Dr. Kuller can --

22

23 DR. KULLER: I would like to tell you
24 a little story about this and how things advance.

25 In 1960, I was the medical officer at Marine

1 Corps Schools in Quantico, Virginia, and I was
2 responsible for examining and evaluating marine
3 officers. I became rather bored with this
4 activity rather quickly, so I decided that we
5 might as well do something else. So we
6 introduced rigid sigmoidoscopy,
7 electrocardiogram, cholesterol testing, a digital
8 rectal examination, and eye and hearing exams
9 even though they were not essentially part of the
10 testing, and a modified exercise test so that we
11 would have something to do which would be more
12 interesting. That was in 1960. So it is rather
13 interesting to see the evolution of this field is
14 rather slow and rather intriguing. It is 36
15 years now, I guess, and we are still looking for
16 evidence-based medicine in some of these areas.

17 DR. FLETCHER: Looking for the true
18 answer. Thank you. Any comments or questions?

19 Yes, sir?

20 DR. LUEPKER: Possibly the only
21 finding that surprised me in those that you gave,
22 Mike, was the low level of approval given to
23 glaucoma testing. I would think that that would
24 be such a simple test with good outcomes that
25 that might have a higher level of approval. I

1 think it was given a D, wasn't it?

2 COMMANDER PARKINSON: It was given a
3 C.

4 DR. LUEPKER: C.

5 COMMANDER PARKINSON: And that is
6 except for high risk groups, which are basically
7 some ethnic groups. The evidence that routine --
8 again, the issue here is routine screening of all
9 people in terms of what is the likelihood that
10 doing that you will be able to detect it early
11 enough to prevent blindness and is there evidence
12 there to well -- you notice that was given a 1
13 out of 2 for well-done, at least in the eyes of
14 the task force, well-done and randomized control
15 trials that basically show no evidence.

16 DR. LUEPKER: I am surprised.

17 DR. FLETCHER: I thought he was going
18 to tell us if he found any pathology in two years
19 of doing it.

20 DR. KULLER: The problem is we didn't
21 perforate anybody's rectum or colon. That was
22 significant.

23 DR. LUEPKER: So the morbidity was
24 low. I actually had a question. One of the
25 things you said was that expert panels were kind

1 of at the bottom of the list for importance. And
2 having served on a number of those expert panels,
3 and I am sure others in the room have, I do have
4 a question about that. I think many expert
5 panels, i.e., consensus conference of the NIH,
6 spend their time reviewing the scientific
7 evidence. This is not a group of specialists
8 just spouting what they think about an issue.
9 And you have, I would suggest, tended to ignore
10 some of those and perhaps weight them lower. And
11 the one I think about as a specific example
12 because I served on it, was the consensus
13 conference on HDL and triglycerides. And I guess
14 I would argue HDL is not an unreasonable thing to
15 include. And I would take the line of reasoning
16 here that although we don't have a prospective
17 clinical trial and while we may, because there is
18 some going on, I would still suggest that the
19 overwhelming weight of evidence is there.

20 And let me extrapolate a bit further.
21 I think that for many things, if we were waiting
22 for a prospective clinical trial on cigarette
23 smoking, we don't have one. And I wonder by your
24 criteria if we wouldn't say, well, we have to
25 wait before we can give any advice on this. We

1 never will have one, but the weight of evidence
2 suggests we do that. So I guess I have a concern
3 about a specific item, HDL, and I wonder if some
4 of the areas aren't being perhaps eliminated for
5 less than what might be agreed evidence in the
6 community.

7 DR. FLETCHER: Well, I appreciate your
8 comment. I personally have an interest in HDL,
9 but we were looking at all the evidence and
10 trying to put this together, and the way most of
11 these people, agencies and everything, not just
12 looking at specialty agents only but very
13 globally. So, I really believe
14 -- the smoking, again, a typical example. There
15 is no proof if you have a randomized trial, but
16 who is going to do that in today's health care.

17 COMMANDER PARKINSON: I might say that
18 the task force methodology is good for many
19 things and as you point out it is not good for
20 everything. There are many areas that what they
21 have done here is basically defined as much of
22 the continuing research agenda in key areas that
23 Dr. Kuller mentioned. And at the very best, this
24 methodology should apply only to the minimal
25 recommendations. And in those areas where the

1 science is evolving and we are not just going to
2 have that much time, that is definitely an area
3 where those other groups need to do it. I,
4 myself, as I look at my personal -- not that it
5 is just my personal view of the cholesterol HDL -
6 - I see a lot of evidence out there that is
7 moving more towards saying -- I mean NCEP and Dr.
8 Kuller -- a cholesterol without an HDL is
9 probably not really what you want to have. I
10 know in the Air Force, for example, we routinely
11 measure HDLs as part of our coronary artery risk
12 evaluation program. So we have already done that
13 even if it doesn't appear in a Tricare Prime
14 benefit. I agree with you.

15 DR. FLETCHER: The National
16 Cholesterol Education Program still designates,
17 unless they have recently changed, HDL as a
18 lowest risk factor. If it is high or above 35,
19 there is a non-risk factor, as I understand. It
20 is not as LDL being high, which is a risk factor.

21 But HDL a non-risk factor if it is greater than
22 35. Dr. Gwaltney?

23 DR. GWALTNEY: We are talking about an
24 art, which is the art of the practice of health,
25 of health promotion as opposed to the art of the

1 practice of therapeutic medicine. And from a
2 historical perspective, which was brought up
3 earlier and they mentioned William Welch, he
4 recruited Wayne Hampton Frost as his first
5 professor of epidemiology at Johns Hopkins
6 School. And he has a wonderful article about
7 when you incorporate items into the practice of
8 health promotion and points out from a practical
9 sense point of view that you do it when there is
10 a consensus. And that is the best we can do.
11 And I thought that was a very fine review of PSA
12 testing and a general overview of the entire
13 field at this time.

14 It will change as data comes in and we
15 change our practice and our art changes. That is
16 the way it should be. There are two other
17 things, though, that I think are extremely
18 important that weren't -- that I have questions
19 about. Number one, who is going to do this? Who
20 actually is doing this in the service or who
21 should do it in the service? And where is it
22 going to be done or where is it being done?

23 We have a program at the University of
24 Virginia now in its sixth year that offers health
25 -- the practice of health promotion to our 12,000

1 faculty and staff, and that incorporates two what
2 I think are very important parts of this program.

3 Number one, it is not done by physicians, and
4 neither of these originally was our program. It
5 is not done by physicians. That is not, I think,
6 an efficient way to use a physicians time. Now,
7 of course if you've got to listen to a diastolic
8 heart murmur, I don't know if you are going to
9 train these health risk technicians or assessment
10 technicians to do that, and this again is part of
11 the art. But it is not done by physicians, and
12 it is done at the work site. So the assessors go
13 out to the buildings and grounds department, the
14 history department, and the law school and that
15 kind of thing.

16 So what is being done in the military
17 in this regard? Is this being done all by
18 physicians and are the people coming in to
19 central facilities or is it being done out in the
20 field or at the work sites?

21 DR. FLETCHER: Comments or answers on
22 that from the Army or Navy?

23 CAPTAIN TRUMP: Dave Trump for the
24 Navy. I think the basic question we are looking
25 at is as a big organization with over 600,000, at

1 least military active duty, is some help about
2 what we should have in our routine physicals.
3 And I think all the services have a requirement
4 for routine physicals at some periodicity. For
5 us, it is at a minimum of every five years. And
6 right now, most of those are being done by having
7 the person come in to a medical treatment
8 facility, being seen by in most cases now
9 physicians assistants, but frequently by a
10 physician or possibly by a nurse practitioner.
11 And what are the things that should be done on a
12 periodicity of every five years with a several
13 100,000 plus population that are being served.

14 I think we have made progress. We
15 have, at least on the Navy/Marine Corps' side,
16 adopted some of the screening guidelines from the
17 first task force into our program so it is more
18 structured along that line. But I still have
19 concerns that it becomes an administrative
20 procedure that we need to get shifted so that it
21 really becomes more of an opportunity for health
22 promotion and for counseling. Maybe the
23 listening to the heart and those things don't
24 need to be just a routine documentation. I think
25 we waste a lot of time doing that and not

1 providing the more significant time, one-on-one
2 frequently with the physician, because I think
3 there is some power in doing that in providing
4 counseling to an individual.

5 DR. GWALTNEY: Certainly, you've got
6 special needs with pilots and there are other
7 things where full physicals would be the
8 appropriate thing to do. In terms of the large
9 numbers of people that you are dealing with, it
10 seems like that would be reasonable to think of
11 other ways. The whole key thing is just to bring
12 the person in contact with the health care
13 system. That is what we are trying to do. And
14 to find out the best way to do that for the best
15 groups of people with the best periodicity. I
16 think that is where the greatest opportunities
17 are to improve what we are doing and to really
18 reach everybody.

19 We should do this for everybody in the
20 country. Really. We know these things work. We
21 know that from studies done in the last 30 years.
22 We can list the things that you had up there
23 that work, and yet there are huge numbers of
24 people in the country that this isn't done. And
25 we should do it routinely for everybody.

1 DR. FLETCHER: The military can be an
2 excellent model. Dr. Kuller?

3 DR. GWALTNEY: The military is a great
4 way to start.

5 DR. FLETCHER: Yes, sir.

6 DR. KULLER: I think you have two
7 different issues here it seems to me. I think
8 that for military personnel who are fairly young,
9 your primary concern has to be looking for
10 familial disease. That is, I think you really
11 need to take a look, for example, at how many
12 colon cancers you are getting in the military and
13 military personnel who are under 50 or 55. My
14 suspicion is that the vast majority of those are
15 familial related and every one of them basically
16 is an error in the health care system. Because
17 in essence you can find to treat that particular
18 problem. When there are a couple hundred colon
19 cancers and maybe 100 deaths each year in
20 Pennsylvania that I just looked at from colon
21 cancer under the age of 50, almost all of those I
22 think are going to turn out to have some genetic
23 disorder that we can identify right now and in
24 essence are preventable both by colonoscopy and
25 also by a variety of procedures to essentially

1 eliminate that mortality.

2 In prostate, I think the issue is
3 rather interesting. If you look at prostate, it
4 is not a hell of a lot different than breast in
5 many ways. About 30 percent of women probably
6 have occult breast cancer which we find by
7 mammography, and an awful lot of the
8 mammographics, especially in older women over 60
9 or 70, turn out to have breast cancer which isn't
10 going to do very much. Yet, we do mammography
11 because we have evidence of a 20 percent
12 reduction in mortality. In prostate, we may not
13 have that right now, but we also don't have
14 evidence that it is not effective. So we are in
15 a situation right now where we really don't know
16 the answer.

17 I would question the statement that
18 you wouldn't want to do radical prostatectomy on
19 a 70-year-old man. I think that the world is
20 changing fairly rapidly, and there would be a lot
21 of 70-year-old men out there who are playing golf
22 every day and living it up and enjoying life
23 after retiring at age 68 who would not be very
24 happy about somebody saying they are finished at
25 age 70 or 75. I think they would say they have

1 got a lot of years ahead and they would prefer
2 not to die from metastatic prostate cancer if
3 that really is true. So I think you have to look
4 at it in the context of the fact that we have an
5 aging and very healthy aging population, which is
6 costing a lot of money to take care of but still
7 happens to be a fairly healthy population of
8 older people.

9 I think one thing you need to do in
10 the military it seems to me, or in terms of
11 preventive medicine, is to begin to focus a
12 little bit more on high risk and simple ways of
13 collecting that kind of data in the sense that
14 PSA testing on a single shot may not be very
15 good, but a rising PSA level in an individual may
16 be a cause of considerable concern. In younger
17 people, it is a cause of great concern. And in
18 some populations, obviously, it is a cause of
19 even greater concern. So I think you may want to
20 look at familial associations.

21 We have also talked about this in
22 terms of coronary disease. The problem with
23 coronary disease in the military and young people
24 is that 60 or 70 percent of the deaths are going
25 to be out of the hospital. People are going to

1 drop dead and it is very hard to provide good
2 clinical care at that moment. So that in essence
3 you want to find those people. Some of that is
4 genetic and familial. I am not sure we are
5 looking for that. And that, again, is a tragedy
6 when a 50-year-old person dies or even has a
7 myocardial infarction and loses part of their
8 left ventricular function and then has disability
9 after that when it potentially could have been
10 preventable. That is an important issue. On the
11 other hand, for many people how have no family
12 history or who have no risk factors, doing those
13 measurements may be of limited value.

14 So I think I would suggest that one
15 thing to do might be to go back and look in the
16 military at actual events that have occurred and
17 try to piece together how those occurred. How
18 much of the -- how many colon cancers do you
19 actually have in the active military each year?
20 How many prostate cancers do you actually have?
21 Where do they come from? What are some of the
22 characteristics of those individuals? Could they
23 have been identified? Could you then use that
24 type of information to improve your preventive
25 screening, rather than making this a general

1 benefit. But rather, preventive screening to
2 identify the highest risk individuals in the
3 military who might benefit from potentially more
4 active identification or better education.

5 DR. FLETCHER: Dr. Cunnion?

6 CAPTAIN CUNNION: Steve Cunnion, U.S.
7 Navy. I have two -- one statement and one
8 question. One of the problems with screening is
9 we get dressed and epidemiology becomes academic
10 in the sense that what we want to do is not what
11 people do. And when we get into screening and
12 cost effectiveness, we have a problem with low-
13 risk people flooding the system, and the high
14 risk people can't get into the system because the
15 low-risk people are flooding it. And that has
16 something to do with personalities of high risk
17 people, if you are doing the socioeconomic levels
18 and stuff. People don't want to wait around.
19 People are not truly motivated. They don't want
20 to wait around for two days or three days or 100
21 phone calls to make appointments to do a
22 screening exam. Whereas the people who are low
23 risk and who are very conscious of their health
24 will make those 20 phone calls to finally get an
25 appointment. So we have a problem with dilution

1 of all screening programs because of this. And
2 that is something that is not really addressed in
3 a lot of these academic discussions of screening.

4 The question is because the number one
5 cancer in the military is testicular, is there
6 any -- has anyone addressed this and is it cost
7 effective to do self examination for testicular
8 cancer in the military?

9 COMMANDER PARKINSON: Tricare Prime
10 does include general exam and it is a
11 recommendation for men 18 to 39 -- I think the
12 task force, I am not sure what it is , but it
13 does get a high recommendation just for that
14 reason. I don't have any particular -- now are
15 you asking if it is being done in the military?

16 CAPTAIN CUNNION: It is not being
17 promoted very strongly in the military.

18 COMMANDER PARKINSON: Right. Let me
19 just say that one of the things that we are
20 dealing with -- getting back to Dr. Gwaltney's
21 question a little earlier. You know, Paul Frame,
22 who was a member of both task forces and really
23 is a national leader in the whole are of trying
24 to say how can we put bombs on target, using Air
25 Force terms, or really getting people to do these

1 tests. And he has argued that we have got to
2 change the medical physical paradigm about a lot
3 of this stuff. And he gets in a lot of hot water
4 with his physician colleagues when he suggests
5 the work site and schools are probably better
6 able, particularly to deliver what really works,
7 and that is behavior change. It is not sticking
8 something on the body or sticking something into
9 the body or doing something with a high tech
10 piece of equipment. So that is absolutely right.

11 I can tell you in the Air Force, we
12 are going through a very healthy but painful
13 reevaluation of what we call our primary care
14 platform. Who is in it? What services do you
15 offer? How do people access it? Do we need, for
16 example, a physical exam section anymore in the
17 historical sense of line them up and do all this
18 stuff to them and they go through and get the
19 hernia check? I know we have all been veterans
20 of this thing. Is that an anachronism? When you
21 talk about a comprehensive primary care platform
22 that accesses a health and wellness center that
23 has nutritional counseling, that has fitness
24 exercise physiologists, et cetera. Yet, the
25 system as a whole is going to be held accountable

1 because that is basically what is happening in
2 the real world. I mean you measure as a federal
3 employee what plan you go into, and one of the
4 measures given to you is how well they perform on
5 health employer plan data information set. HEDIS
6 indicators of which 4 of 7 are those very
7 services that we talked about -- immunization
8 rates, pap smears, cholesterol, and mammograms.

9
10 So this whole area -- the charge for
11 us working in this system is how do we make sure
12 the system performs to deliver these essential
13 services using less manpower that we are going to
14 have than we had five years ago, but we've got to
15 make the system work for us. And that is the
16 very issue we are working with.

17 DR. FLETCHER: Another question. Dr.
18 Luepker?

19 DR. LUEPKER: Yes. Several people
20 have touched on what I think is a critical issue,
21 which is unique issues to this population. And
22 the things you have talked about are things that
23 are issues in the general population for
24 screening, but have you looked at all or
25 considered the data that you have on your

1 population. We talked about testicular cancer a
2 moment ago. Things that would be particularly
3 both important and high yield in a population
4 that is predominantly male and predominantly in
5 the less-than-Medicare age group. I mean are
6 there unique things to help make this population.

7 COMMANDER PARKINSON: If I basically -
8 - you've heard the presentation by Bruce Jones,
9 and you will hear the final one. We've got a
10 young male population. It is injury, it is
11 alcohol. We have both self-reported data,
12 consumption data, and everything to show. If I
13 had bombs on target to improve the health of the
14 force and decrease mortality, it would be better
15 detection or use of standardized screening
16 instruments to follow-up for alcohol-related
17 conditions. In the area of cancers, we do have
18 five years of information in the Air Force now
19 about illness causes of death by cancer rates.
20 And basically we are looking at that in terms of
21 morbidity, mortality, and disability.

22 I will tell you something about the PM
23 update a little bit. I won't give you the
24 numbers for what we are doing. And that is
25 exactly right. But when we look at what people

1 are dying of in active duty, it is motor vehicle
2 accidents, it is basically suicide/homicide. It
3 is all of those things of which there is a 30 to
4 60 percent alcohol-attributable fraction related
5 to that. So we get into those issues.

6 DR. ASCHER: An interesting follow-up
7 to the Gulf War hearings I went to. Illness was
8 exactly that, Mike. Where you looked at the
9 overall mortality of people who were deployed to
10 the Gulf, and it is actually very low compared to
11 a similar cohort for obvious reasons, but it is
12 much lower in areas of heart disease and
13 infectious disease and all of the things that we
14 think about, but it was offset by a very strong
15 increase in alcohol-related motor vehicle
16 accidents, as you said. So one of the preventive
17 measures if I have people coming back from
18 deployment is I might give them a little driver's
19 training. Because there were like 200 excess
20 deaths, and that is a hell of a lot of people in
21 terms of what we are concerned about of this
22 overall problem.

23 DR. FLETCHER: Dr. Joseph?

24 DR. JOSEPH: Well, I think
25 unfortunately the discussion about the

1 denominator is just wrong. Of our 8 and a third
2 million patients, less than 20 percent are active
3 duty, and an increasing percentage of those
4 active duty are female, and our fastest growing
5 population is in the retiree community. And
6 among those, the fastest growing population is
7 the over-65's. So I think we are not talking
8 here about what to do with healthy young male
9 recruits who have over-use syndromes. We are
10 really talking about a much broader preventive
11 question.

12 And I think at the risk of making the
13 review more difficult, I think there are really
14 three things you need to do. I think this is
15 useful and important. Your presentation was
16 terrific, Mike. But I think this is only really
17 the surface. I think you really do need to take
18 your recommendations and disaggregate them by age
19 because of the demographics that I just
20 described. And there may be other ways to
21 disaggregate your subpopulations that you need to
22 do.

23 Second, I think you do need -- going
24 back to Dr. Gwaltney's comments -- I think you do
25 need to give us some help on the issues of

1 setting and periodicity. I mean we are building
2 a managed care system, and I think it is a very
3 real question whether we want to segregate off
4 preventive and screening measures into a non-
5 physician work site or whatever context or
6 whether we wish to use the consultative primary
7 care emphasis of the system as a basis for both
8 screening and/or counseling.

9 And then thirdly, I would like to see
10 you give us some recommendations around
11 counseling and broader environmental
12 interventions related to prevention, in this case
13 for men but you could even broaden that to the
14 entire population. For example, it may well be
15 that the counseling intervention around smoking
16 and tobacco use is not the key intervention that
17 we should be pursuing in the military currently.

18 That is hazardous ground for me to tread on, but
19 if you are not going to tread on it, how can I
20 tread on it.

21 So I think you really do need to take
22 this good start, which is a kind of clinically
23 examination focused approach to screening and
24 broaden it out into at least those other
25 dimensions and give us back a much more rounded

1 picture of advice. This, for example, might be
2 one of those areas that the board wants to take,
3 like the occupational issue, and weave it into a
4 longer term approach by which you then could go
5 back and do some real epidemiology in our system
6 and take that back and modify it, et cetera. I
7 don't think this is kind of a simple, one shot,
8 yes we should screen for this but no we should
9 not screen for the other.

10 DR. FLETCHER: I appreciate that. I
11 think we really purposefully sort of left out the
12 age levels or frequency, and this really has to
13 be tailored to all those at the next
14 consideration. Our time is essentially up, isn't
15 it, Dr. Kuller?

16 DR. KULLER: I think it is about time
17 for the break. I think it is 9:50? Is it really
18 that?

19 (Whereupon, at 9:52 a.m. off the
20 record until 10:21 a.m.)

21 DR. KULLER: Can we sit down, please,
22 and get started?

23 COLONEL FOGELMAN: Can we have
24 everybody's attention? Please take your seats.

25 DR. KULLER: Lt. Colonel Defraites is

1 going to continue on the Bosnia update.

2 COMMANDER DEFRAITES: Thanks, Dr.
3 Kuller. My purpose this morning is to update the
4 Board on some of the policies and plans for
5 preventive medicine coverage for the troops in
6 Bosnia as well as some of the policies that are
7 in place for some surveillance activities,
8 including post-deployment surveillance. And then
9 I will give a little update on what some of the
10 more interesting aspects of some of the
11 preventive medicine problems that have occurred
12 so far in the deployment.

13 In terms of the pre-deployment
14 preparation -- and some of the policies that I
15 will be talking about this morning are included
16 in a number of messages that have been
17 promulgated by the Commander-in-Chief of the
18 European Command, this is four-star General
19 Joulwon, who has overall responsibility for the
20 theater. So his surgeon's office has promulgated
21 certain policies. Also, Dr. Joseph's office in
22 the Department of Defense as well as the Services
23 have collaborated on some of the other
24 surveillance policies.

25 Just last Friday, the European Command

1 put out a message directing post-deployment
2 surveillance activities, and I will describe some
3 of those too.

4 In terms of the pre-deployment
5 preparation, I have divided them up into these
6 five subject areas of threat assessment,
7 preparation of a registry of personnel deploying,
8 some screening activities, some health education
9 and training, and immunizations.

10 In terms of the elements of the
11 medical threat, and these are prioritized
12 generally by the preventive medicine community,
13 from top to bottom. First of all, going into
14 this theater, I think trauma was the number one
15 concern, both the extensive use of land mines in
16 the area as well as the typical motor vehicle
17 type collisions or motor vehicle accidents from
18 the poor road conditions as well as maybe the
19 operational tempo in setting up the camps.

20 Secondly was climate, especially at
21 the time of year that the deployment started in
22 mid-December. The cold injuries were very much a
23 concern in terms of a preventive medicine threat.

24 We are also concerned about the possibility of
25 heat injuries in the summer as well as some

1 consequences of heating tents and buildings in
2 the wintertime.

3 In terms of infectious diseases, there
4 was, as previously alluded, some concern about
5 the arthropod-borne diseases, especially tick-
6 borne encephalitis. But also because of the
7 impaired infrastructure in the Bosnia-Herzegovina
8 area, enteric infections are always a military
9 threat, especially in this theater. Then we were
10 concerned about some person-to-person spread
11 diseases such as tuberculosis and other
12 respiratory diseases including a widespread
13 influenza epidemic ongoing in the Balkans. And
14 finally, the rodent-associated diseases,
15 especially the hantaviruses.

16 Finally, because this is a relatively
17 industrialized area, we are concerned about some
18 of the environmental threats such as pollution of
19 soil, water, and air.

20 In terms of the registry, again
21 mandated by the surveillance plan, a deployment
22 roster of all military personnel deploying to the
23 theater is being created by the Defense Manpower
24 Data Center through the J-1. The J-1 is the
25 proponent for personnel issues at the Joint

1 Staff. This data base will include the
2 individual identifiers, the unit codes of the
3 unit that the person deploys with, as well as the
4 dates of deployment and return. And also
5 maintenance of a serum archive. The Army/Navy
6 serum repository where up to 17 million specimens
7 linked by a personal identifier and the date of
8 draw are available as a pre-deployment baseline
9 serum if needed for later epidemiologic studies.

10 In terms of screening activities for
11 the troops before deployment, all troops were
12 required to have a DNA specimen on file. This
13 DNA is in a registry at the Armed Forces
14 Institute of Pathology, and its purpose is for
15 forensic identification of remains only. For the
16 same purposes, a dental panographic x-ray is
17 required to be on file. Troops were required to
18 have a negative PPD skin test for tuberculosis
19 within the 12 months before deployment. A
20 negative HIV test within 24 months before
21 deployment. And for women, a negative pregnancy
22 test before immunizations. This was a U.S.
23 Army/Europe requirement, USAREUR requirement,
24 that was added to the EUCOM requirements.

25 In terms of health education and

1 training, for troop health education, there were
2 information booklets for soldiers, leaders, and
3 medical planners that were produced by the Army's
4 Center for Health Promotion and Preventive
5 Medicine, that is the CHPPM, and also the Medical
6 Research Material Command collaborated on these
7 booklets.

8 In terms of training, especially over
9 in Europe, since the bulk of the troops deploying
10 initially were 1st Armored Division troops from
11 Germany, field sanitation team certification
12 through the U.S. Army/Europe was stepped up in
13 advance of the deployment. And EUCOM, the
14 European Command dictated that there would be a
15 preventive medicine briefing given to all troops.

16 I am not going to bother with the details, but
17 this preventive medicine briefing was to cover
18 the following topics: endemic infectious
19 diseases, food and water precautions, field
20 sanitation, et cetera. Some of the same issues
21 identified in the medical threat.

22 Finally, in terms of immunizations,
23 not a long list here. Troops were required to be
24 up to date on the routine adult vaccines such as
25 tetanus and polio, typhoid, and the current

1 year's influenza vaccine. This is normally
2 required for troops anyway. They also were to
3 receive a Hepatitis A vaccine or a gamma globulin
4 Hepatitis A vaccine was preferred. And also at
5 the time and still was the consideration of tick-
6 borne encephalitis vaccine. We have already
7 heard about that issue this morning.

8 In terms of the other preparations for
9 troops, and this addresses some of the other
10 concerns and risks, cold weather protective
11 clothing was issued to all troops, and arthropod
12 repellents were emphasized in the messages and
13 since then use of permethrin impregnation of the
14 uniform, the use of a DEET skin lotion as a
15 repellant, and also troops received a typical
16 type of medical preparations, two pairs of
17 eyeglasses if you need them. People who don't
18 wear eyeglasses don't need to bring two pairs.
19 That is not as plain as it may seem. Your
20 hearing protection and if you need hearing aids
21 and batteries. Now to switch to exactly
22 the theater itself. This is a slide that is a
23 little busy. The details are not important. But
24 this shows you the area that is occupied by the
25 troops. This is the southeastern portion of

1 Hungary, the sort of eastern arm of Croatia, and
2 the U.S. sector of Bosnia-Herzegovina. The
3 landmarks are Sarajevo down here, Tuzla in the
4 center of the U.S. Sector, the Sava River, the
5 famous bridging operation over the Sava River,
6 which I will get to in a few minutes, and then
7 the staging area. The logistics base at Taszar
8 and Kaposvar in southern Hungary. This is where
9 a lot of the logistics components are, and there
10 is a large medical component. All of these
11 little boxes with the cross in it indicates a
12 medical unit. And in Hungary is the combat
13 support hospital and the associated units there
14 at the staging area. There is also a Level 3
15 facility, the 212th MASH in Tuzla, and a number
16 of other units there. I might come back to this
17 slide in a few minutes.

18 In terms of what preventive medicine
19 activities and preventive medicine units are
20 there presently -- in terms of the tactical
21 preventive medicine direct support, there are two
22 Army units that are there in strength, and that
23 is the 71st and the 133rd Med detachments. Those
24 are both preventive medicine units. They are
25 split up between the staging area in Hungary and

1 the Tuzla area. They provide -- and also the 1st
2 Armored Division has its own preventive medicine
3 officer and preventive medicine technicians.
4 They provide water and sanitation, pest and
5 vector control support. In terms of water
6 surveillance, they check chlorine levels and do
7 some limited water testing and also provide some
8 of the inspection of the food service facilities,
9 and finally some of the medical activities.

10 Now in addition to those usual units
11 that are in place, and that is typical by
12 doctrine, the 520th Theater Army Medical
13 Laboratory -- this is a newly activated Army unit
14 that was just activated in September, and there
15 are 10 personnel from the TAML, I will call it
16 from now on, that are in Tuzla. They are co-
17 located with the 212th MASH. There is an
18 epidemiologist and infectious disease physician,
19 a microbiology lab, and an environmental sampling
20 capability. There is also, in addition to the
21 520th TAML, is a special air sampling/air
22 pollution sampling team that had gone into some
23 of the areas of Bosnia as well as some enhanced
24 water evaluation. As I mentioned, the tactical
25 preventive medicine units just provide for the

1 most part chlorine residuals and total bacterial
2 counts. For this operation, that has been
3 enhanced by shipping water specimens back to a
4 laboratory in Germany for testing of volatile
5 organic chemicals and also the heavy metals. So
6 that is being done as well.

7 In terms of medical surveillance for
8 disease and non-battle injuries, what are being
9 collected are weekly outpatient illness and
10 injury rates, admission rates, reportable
11 diseases, and then focused investigations for
12 special problems. And these are mainly going to
13 be based out of that theater Army medical
14 laboratory. That is sort of the fire power for
15 doing a lot of this work, or at least for
16 overseeing the effort.

17 In terms of some of the data that is
18 available so far -- at least just some of it that
19 I wanted to review. Hospitalization rates for
20 Operation Joint Endeavor, and the week of
21 deployment here this is essentially the number of
22 hospitalizations over the number of troops
23 deployed in theater. And the week of deployment
24 would be from the end of December. So we have
25 weeks 1 through 9. This is a rate per 10,000

1 soldiers per week. You can see there is a blip
2 here in week 3, and I will get to that in a
3 minute of what that is.

4 Here is the breakdown by just general
5 category of what type of admission it was. These
6 are based on admission diagnosis only. So you
7 can see that the bulk of admissions have been for
8 sort of all other diseases other than the non-
9 specific, non-infectious disease, non-psychiatric
10 type of admission.

11 UNIDENTIFIED AUDIENCE: Could you
12 raise that up, please?

13 COMMANDER DEFRAITES: Oh, sorry.
14 Let's see. Everybody has seen the top, so how
15 about that. I'm sorry. I will start again. The
16 largest category is the all other medical, it is
17 20 per 10,000 per week.

18 DR. KULLER: What is that really?

19 COMMANDER DEFRAITES: That is a mixed
20 bag. Usually it represents observation for belly
21 pain for possible appendicitis that is ruled out,
22 headache overnight release, and that type of
23 thing. It is a mixed bag. It is things that
24 aren't -- maybe -- Colonel Brundage is raising
25 his hand. He can --

1 COLONEL BRUNDAGE: The other thing I
2 suspect is since this is the admission diagnosis
3 is that after an evaluation is done a lot of
4 those all others will be redistributed into
5 infectious and other more specific categories.

6 DR. JOSEPH: I think the key thing is
7 on a weekly tracking rate that we have, the
8 hospitalization rates and the category of
9 diagnosis rates are similar or lower than the
10 current peacetime DNBIs.

11 COMMANDER DEFRAITES: Another feature
12 of the surveillance plan is that of linking the
13 deployment personnel roster that I alluded to
14 earlier with the Army's medical surveillance
15 system disease reports. The Army has got an
16 automated reportable disease bulletin board
17 system that can link by identifiers so that we
18 can track reportable diseases that are reported
19 to this bulletin board with the deployment
20 roster. And also it is linked real-time to
21 hospitalization databases, including the one that
22 is tracking the hospitalizations from the
23 hospitals in Hungary and Bosnia as well as all
24 military hospitals worldwide.

25 And finally, there is plans to link it

1 up with the disability data base at a later date.

2 So once this -- of course the deployment
3 personnel roster for Bosnia is not complete yet
4 because we still have quite a few more troops
5 deploying over the summer until this operation,
6 assuming it is going to be a one-year operation.

7 The data, once it is finalized, will be
8 available to be linked to these hospitalization
9 data bases for look-backs at a later date.

10 The final part of the surveillance
11 effort that I wanted to review is the post-
12 deployment piece. In general, it is a medical
13 evaluation and counseling before leaving theater
14 along with some psychological stress screening
15 instruments as well as the collection of a serum
16 specimen. Now there has been more detail to this
17 flushed out since European Command has just
18 Friday put out their message about how this was
19 going to be done. And I divide this up into the
20 requirements for troops before they leave the
21 theater. Right now what they are planning to try
22 to do is to draw and ship a 10 cc red-top tube, a
23 serum specimen, from the theater and to fill out
24 -- this SF-600 is a standard medical form and it
25 has got some medical questions that have been

1 designed specifically for this deployment. It is
2 basically a medical screening type of
3 questionnaire. They are supposed to -- they are
4 going to be delivering a threat brief, basically
5 giving the troops information on what medical
6 problems and threats have been identified in the
7 theater. They will put some of this into writing
8 and distribute it to the troops as they redeploy.

9 And finally, the psychological screening
10 includes a Penn, which is a post-traumatic stress
11 disorder scale. The CAGE alcohol use index and a
12 Zung depression scale.

13 Now at home station or some other
14 point -- right now, the plan calls for -- and,
15 again, this is still in some level of negotiation
16 of exactly what has to take place where. But
17 right now, the plan calls for within 30 days of
18 redeployment, troops are supposed to have any
19 theater requirement that wasn't, for whatever
20 reason, met in theater, they are going to have it
21 done. So there is a make-up. And then they are
22 supposed to get an updated briefing on the
23 medical threat if anything has changed since they
24 left the theater. A fact sheet -- now this fact
25 sheet is supposed to have local phone numbers for

1 medical points of contact at the home station and
2 other local resources such as family support and
3 whatnot.

4 And then they are also supposed to
5 complete this DD Form 2697, which is another
6 medical screening questionnaire. And then
7 finally at 90 days a tuberculosis skin test.

8 The final piece is a data file is
9 going to be created from this redeployment work
10 and ASCII text files will be made with the unit
11 of assignment, the date post-deployment screening
12 was completed, the last name, first name, middle
13 initial, and Social Security number. And this is
14 going to be collated at EUCOM surgeon's office.

15 Now I wanted to turn to one of the
16 more interesting aspects of the deployment and
17 that was an outbreak of a rash illness that was
18 reported between Christmas and New Year's as the
19 first troops went in to Bosnia and were trying to
20 put this bridge across the Sava River. It was a
21 pretty dramatic time and sort of a sideline to
22 that was this rash illness. The work and the
23 report that I am going to deliver has been done
24 mainly by Jim Cook, who is our epidemiologist at
25 the Center for Health Promotion and Preventive

1 Medicines detachment in Europe.

2 This investigation is still ongoing.

3 To give you a little bit of background, the
4 engineer units that were deploying to Bosnia,
5 before they went to Bosnia or to the Sava River
6 site, they had to go to a site in Germany to have
7 some training in like mine detection and
8 avoidance and then they had to draw some
9 equipment from a storage site in Belgian. All of
10 this took about 10 days before they were actually
11 able to deploy to Bosnia itself. These units -
12 now the engineer units came from Germany and also
13 came from the United States, and they were
14 assisted at the Belgium site to draw the
15 equipment by units that were stationed in Belgium
16 and the Netherlands at a full-time station there.

17

18 Rash illness outbreak occurred among
19 the engineers and the support units. Just to
20 give you sort of a little time line in some of
21 the units, this slide was prepared by Rob Lipnick
22 who is on the joint staff. What I have here is
23 in blue is the first unit that was affected was
24 called the 586th Engineering company. In red is
25 a 362nd Engineer Company. And the final one is a

1 55th Medium Girder Bridge Company, another
2 engineer company. We have very specialized
3 engineer units that work quite well. They just
4 sometimes locate their camps in unfortunate
5 places near where rivers flood.

6 The 586th Engineer Company was the
7 first engineer company that was affected. They
8 spent -- they left the continental United States
9 on December 13. They stayed at this resort hotel
10 -- it is basically a contract hotel for troops
11 that are drawing units from this CEGE site. I
12 don't know what the CEGE stands for anymore, but
13 that is the storage site -- between the 20th and
14 the 26th of December. They took a train to
15 Hungary between the 27th and 29th. The first
16 case occurred on the 28th. So anywhere between 2
17 and eight days after staying in the hotel and
18 drawing their equipment from the sites, they
19 developed the first case. Within the next three
20 days, they developed -- well, within the next
21 week or so, they developed 27 cases in total.
22 The unit was isolated for a few days and then
23 returned to duty.

24 The second unit was affected in
25 January. The same story. They stayed at this

1 resort hotel and drew the equipment from the site
2 between the 11th and 17th of January. They
3 developed their cases about 8 days later after
4 being at the hotel. And then finally a similar
5 story with this third unit that left the United
6 States on January 2 and was at the site
7 overlapping with this second unit.

8 The initial observations about the
9 rash were that it was a non-severe illness. It
10 seemed to be self-limiting and at first the
11 symptoms that were thought to be associated were
12 a rash, fever, and sore throat. However, on
13 further work-up -- well, let me just tell you a
14 little bit about the investigation. From
15 Landstuhl Medical Center and also from the CHPPM
16 Europe, there were two teams that were sent to
17 investigate the units. The investigation here
18 was of the third unit that I mentioned on the
19 slide. Three physicians -- preventive medicine
20 physician, infectious disease, and a
21 dermatologist. And then from Landstuhl a team
22 went up to Belgium to investigate the site.

23 Then laboratory studies were done at
24 the CHPPM at Landstuhl Regional Medical Center,
25 here at WRAIR, and other labs in the Medical

1 Research and Material Command. The investigation
2 covered the following areas. In terms of food
3 and food sanitation, the drinking water and the
4 pool at the hotel, any possible industrial or
5 chemical exposure since this equipment site
6 seemed to be implicated originally, any
7 immunizations or medications that people were
8 taking and any kind of vector-borne disease such
9 as rodent-borne disease or insect or any
10 reservoirs and also what leisure activities these
11 guys may have engaged in.

12 The period of onset was between the
13 20th of December and the 24th of January. By the
14 time the units arrived in Belgium to onset of
15 symptoms was about 8 days. The overall attack
16 rates were 69 out of 466 in these units, so about
17 15 percent. Of the hotel staff and combat
18 equipment companies -- so these are kind of the
19 support units right there -- one of the support
20 units right there in Belgium at the site, 0
21 percent. Engineer companies between 9 and 20
22 percent and other support units between 27 and 31
23 percent.

24 In terms of risk factors for being
25 associated with the rash, age, gender, MOS, which

1 is the military occupational specialty, the rank
2 or what platoon or squad or unit you were in was
3 not associated with the rash.

4 A little bit more about the clinical
5 details. The rash itself was an erythematous
6 macular rubelliform type rash that was mildly
7 pruritic and mostly on the proximal limbs and the
8 trunk. At first we thought that it was a febrile
9 rash illness and later looking at the data, it
10 doesn't seem like the URI symptoms are associated
11 with the rash. In other words, the frequency of
12 these upper respiratory type symptoms among
13 patients with the rash is no different than the
14 frequency of URI symptoms in other people in the
15 unit that didn't have a rash. So it seemed to be
16 strictly this rash. There were not many reported
17 insect bites. Fever was 30 percent reported.
18 None were documented. The loss of duty time was
19 a majority of one day and the reason for seeking
20 medical care was the majority because of command
21 interest. This generated a tremendous amount of
22 command interest because of the need for these
23 engineer units to build these bridges.

24 Those hospitalizations that I showed
25 you in that blip in the middle and the third

1 week, those were soldiers with rash that were
2 admitted for observation at the 67th CASH, the
3 67th Combat Support Hospital in Hungary.

4 So in summary, we had a fairly large
5 outbreak of a rash with plus or minus mild
6 symptoms. They are still looking as a probable
7 infectious etiology with a point source exposure.

8 Because there was very little propagation within
9 the units. The cases would crop up over a few
10 days and then not propagate within the unit any
11 further. So there didn't seem to be any person-
12 to-person transmission.

13 The common exposure among the cases
14 was the hotel. Not the equipment site but the
15 hotel. Because the unit that was at the
16 equipment site that didn't stay at the hotel
17 there were no cases. They have changed now the
18 hotel that was being used and there has been no
19 cases since other housing arrangements and the
20 investigation continues.

21 Viral cultures were collected on a
22 number of the troops that came from Belgium and
23 the Netherlands as well as those from Hungary,
24 and the results so far indicate there is no --
25 these were throat, rectal, and urine cultures,

1 and there has been no virus cultured. The rest
2 of the studies are ongoing. I don't know, John,
3 if you've got any more
4 -- Colonel Brundage has any more details about
5 that. But that is the latest from Bosnia.

6 COLONEL BRUNDAGE: I met Colonel
7 Surgeon in Austria and our lab and CDC do an
8 experimental enterovirus IGM test. We got 22 of
9 the first sets and there are 6 positives screened
10 at a low level.

11 COMMANDER DEFRAITES: IGM for what?

12 COLONEL BRUNDAGE: Enterovirus group
13 IGMs. We don't have any controls. We don't know
14 what the background is in that population. We
15 are not hanging anything on it at this point, but
16 it is not negative. So we have asked for further
17 sera of the uninfected people and we are getting
18 some of the later samples. The problem with
19 enterovirology is there are so damn many viruses
20 and you just can't really test. So what we did
21 is we put an Echo-30 antigen and it reacts
22 reasonably well with that. But in terms of
23 cocci, we think the cross is going to be fairly
24 weak, and this would be consistent with a low-
25 level cross or a background. It is probably a

1 little better than PSA. All I am saying is that
2 this is a very hard field and the next step is
3 picking one of 70 viruses and where do you go.
4 So we are playing with them and we will probably
5 talk to the CDC. They also have a similar test
6 and we will probably share them back and forth.

7 DR. BROOME: Why wouldn't you have
8 secondary spread?

9 DR. ASCHER: Why would you or why
10 wouldn't you? I think that is what they have
11 just demonstrated.

12 DR. JOSEPH: They were isolated. The
13 units were isolated.

14 DR. ASCHER: Isn't that what you were
15 saying? That you had secondary --

16 COMMANDER DEFRAITES: I didn't hear
17 the question. I am sorry.

18 DR. ASCHER: Okay. Why wouldn't you
19 have secondary spread? I think you were showing
20 that or postulating that?

21 COMMANDER DEFRAITES: Well, I didn't
22 show an epidemic curve, but my impression of the
23 case onset -- the onset of illness -- all the
24 cases that would occur within a unit occurred
25 within several days of each other. And they all

1 -- and in all three of these sort of experiments
2 of nature where the units traveled separately,
3 they all seemed to occur within 8 days after
4 leaving the hotel and then not keep spreading
5 within the unit after that 8 day incubation
6 period. That is kind of where I was driving at.

7 Yes, sir?

8 DR. KULLER: You said there were no
9 similar cases among people who work at the hotel,
10 right?

11 COMMANDER DEFRAITES: That is right.

12 DR. KULLER: And what about the hotel
13 -- did the hotel have any people there when the
14 military -- when the U.S. Military isn't there?

15 COMMANDER DEFRAITES: I think they do.
16 But I don't think anybody tried to track down --
17 this was a -- you can understand it was a fairly
18 sensitive issue since it was a Belgian hotel.
19 So, I think they were treading very carefully.

20 DR. KULLER: I have seen one
21 possibility of considerable importance is whether
22 people who go to the hotel and were not in the
23 military also get a rash.

24 COMMANDER DEFRAITES: That is a
25 possibility.

1 DR. KULLER: I mean, that would be
2 rather important. And the other question would
3 be, and I don't know enough about this so it
4 might be kind of silly, but of course one of the
5 problems that happens to people who travel a lot
6 sometimes is that you go to the hotel and you
7 wind up using their sheets or the laundry or the
8 soap that they use or things of that sort and you
9 essentially get a contact type of dermatitis.
10 This is not a contact type of dermatitis
11 associated with exposure to something that they -
12 - the detergent or the soap they used when they
13 took a shower at the hotel or something like that
14 or the swimming pool -- they threw something in
15 the swimming pool?

16 COMMANDER DEFRAITES: Well, the pool,
17 as I understand it, was closed. I was wondering
18 about a hot tub type of dermatitis as well. That
19 is what I was thinking of. No, they had no
20 jacuzzi and the pool was closed when they were
21 there. But the investigation team slept on the
22 sheets too, and they
23 -- of course, it was a small number, not a big
24 enough sample size to really rule that out, but I
25 would wonder if that would wait for eight days.

1 I guess that was the other -- we might expect it
2 to show up sooner than an 8 day incubation
3 period.

4 DR. JOSEPH: I don't know. You know,
5 there were a number of the cases with the index
6 symptoms who had upper and a couple of cases
7 lower respiratory symptoms. And my understanding
8 was from EUCOM that there were anecdotal reports
9 of similar illness with rash among either staff
10 or people who had stayed at the hotel previously.

11 This is -- I don't know what the diagnosis is,
12 but every pediatrician in the house knows what
13 happens every September when kids go to first
14 grade for the first time. My guess is that if
15 you disaggregated that 8-day period into a real
16 curve, you might well find some first and second
17 generation cases. This was good shoe-leather
18 epidemiology, and the issue was one, the command
19 concern about getting these guys to the river to
20 work on that bridge, and two, public interest and
21 hype of the issue, particularly in the wake of
22 the Persian Gulf concerns and the rest. Here was
23 a Belgian mystery disease afflicting our troops.
24 Otherwise, it would not have been a blip on the
25 screen.

1 Let me say two more things while I
2 have it. One, the really interesting
3 epidemiology of this period, that Sava River
4 bridge is an incredible achievement in the
5 circumstances. The real interesting epidemiology
6 is there was not a single case of significant
7 cold injury in these troops or immersion injury
8 in these troops who were for days in the cold and
9 the water and mud of that area.

10 And finally, the real environmental
11 threat, taking that back to your first step, the
12 real environmental weather-related threat I think
13 is probably not the winter that everybody is
14 looking at now but the spring in Bosnia. This is
15 hard-pan clay with a very high water table and
16 the mud is already, even in winter, this deep in
17 the heavy equipment tracks. And when the rains
18 come down into those valleys off those water
19 sheds as things heat up and the bugs come out and
20 the water and the mud get deeper, that is when
21 the real interesting epidemiology is going to
22 occur in Bosnia.

23 COMMANDER DEFRAITES: Yes, sir.

24 DR. FLETCHER: About your
25 hospitalizations. The 21 mental illnesses, how

1 were they characterized?

2 COMMANDER DEFRAITES: I really don't
3 have any details about what their diagnosis was.
4 This was just a broad category based on an
5 admitting diagnosis.

6 DR. GWALTNEY: If I understood what
7 you said, after the troops are finished their
8 mission and are going home, they are going to get
9 psychological stress testing. Are they going to
10 get that as a baseline with the other baseline
11 evaluations they are going to have, and if not,
12 wouldn't that be a good thing to do before they
13 are deployed as well as afterwards?

14 COMMANDER DEFRAITES: Well, a good
15 number of the troops have had a baseline. There
16 is an ongoing project from what WRAIR's European
17 detachment has. Most of their interest is
18 directed in this area and a lot of these troops
19 have that baseline. But for the whole force, it
20 wasn't done.

21 DR. GWALTNEY: Well, when it was done
22 as a routine, was that before or after they knew
23 they were going to be deployed?

24 COMMANDER DEFRAITES: I think it was
25 as part of their deployment. It was directed at

1 people who --

2 DR. GWALTNEY: Is that going to be
3 part of the data base? Is that going to be
4 linked?

5 COMMANDER DEFRAITES: The WRAIR unit
6 is collecting the psychological data. Their plan
7 is to be the collection -- they are going to be
8 the node that collects all the data, and they
9 have the plan for how they are going to look at
10 the data and they have some baseline data to go
11 on.

12 DR. GWALTNEY: Okay. Because you are
13 looking at other risk factors -- other medical
14 risk factors, and it looks like it would be a
15 good idea to look at psychological risk factors
16 before they are exposed.

17 DR. JOSEPH: Well, your point is well
18 taken. The answer to it is that there is not a
19 good denominator comparison on that, nor really
20 on the physical -- true denominator comparison on
21 the physical exam side. I mean, for example,
22 there have been recommendations in the wake of
23 the Persian Gulf that everybody before they
24 deploy get a new, full medical work-up -- medical
25 and psychological, and that really is judged to

1 be prohibitive in logistic terms. What we do
2 have in addition, though, is we have combat
3 stress teams in theater. Again, they won't give
4 you a denominator comparison, but their work is
5 both preventive and consultative. So we may have
6 some interesting numerator comparisons along the
7 way with the troops who are deployed. But there
8 is no true denominator comparison. You are
9 perfectly right. That was just judged to be
10 something we did not want to invest the resources
11 in.

12 DR. GWALTNEY: Because it may come
13 back to get us again if --

14 DR. JOSEPH: Well, it may.

15 DR. GWALTNEY: If there is such a
16 thing as Bosnian syndrome, it may come out of
17 that 1.7 percent that have been hospitalized with
18 the psychological.

19 DR. JOSEPH: Indeed it may, and in a
20 perfect world you might want to do a full work-up
21 with all laboratory tests and tertiary
22 consultation to everybody who is ever going to
23 deploy in any theater, but this is where we
24 decided to draw the line.

25 DR. GWALTNEY: I would think just a

1 simple screening would be good.

2 DR. ASCHER: As I indicated in our
3 other discussions, my understanding is that if a
4 reservist comes home after deployment and ends up
5 with a problem, there is a mechanism for that
6 person to get seen in the system.

7 DR. JOSEPH: And we are keeping the
8 Persian Gulf hotline -- the registry hotline that
9 we have open and turning it into an ongoing
10 registration table.

11 CAPTAIN BERG: Bill Berg, Navy
12 Environmental Health Center. Bob, if I
13 understood you right, a negative PPD test was
14 required to deploy. Does that mean somebody with
15 a positive PPD test, even if they have been
16 appropriately evaluated and perhaps received INH
17 cannot go?

18 COMMANDER DEFRAITES: Well, of course
19 not. I know what I said. I just say what the
20 message says. We try not to take all the
21 clinical tools and judgment from the physicians
22 on the site, but we don't cut them a lot of
23 slack. But we do cut them some.

24 CAPTAIN BERG: In that case, I won't
25 ask my second question.

1 DR. CHIN: Of all of the troops
2 deployed, what percentage, if any, are reserve?

3 COMMANDER DEFRAITES: I think the cap
4 for reserve activations was 3,000.

5 DR. JOSEPH: It is 3,000 plus out of
6 20,000. But the reserves are there on 140-day
7 deployment while the active duty are there for a
8 full year. So there will be three rotations of
9 reserve, or about 10,000 out of about a total of
10 30,000 in the AOR.

11 DR. ASCHER: Could you speak to the
12 Hungary site again? You had the map up, and one
13 of the things we were told, and I gave you lots
14 of anecdotes, was that the region of Hungary was
15 where there would be some R&R. And one of the
16 questions was what do people do when they have
17 R&R. Do they wear their permethrin uniforms
18 inside their boots when they are back in R&R?

19 COMMANDER DEFRAITES: Probably not.
20 Well, if it is at a good time of year --

21 DR. ASCHER: But is that an R&R site,
22 where you have the --

23 COMMANDER DEFRAITES: Oh, I don't know
24 where they are.

25 DR. JOSEPH: Right now there is no

1 R&R, and general order number 1 is no off base
2 and no fraternization. That is a matter of some
3 considerable concern among the troops, but nobody
4 is going off base either in Hungary or in Bosnia,
5 but that will probably change.

6 DR. POLAND: Is this system you
7 described particularly with the pre- and post-
8 deployment sera and briefings, et cetera, going
9 to be in place for each of the services that have
10 troops there?

11 COMMANDER DEFRAITES: Yes. It is
12 designed as a joint -- it is designed to cover
13 all services. When I mentioned European Command,
14 that is a unified command. So everyone -- they
15 make rules for all the services that play in
16 their backyard. That is kind of how it works.
17 So, it covers all the services. Except, there
18 are conditions on this plan in that it is
19 intended for ground troops. So that troops that
20 are afloat -- sailors and troops that never set
21 foot in -- even though they are in the theater,
22 they never go offshore, will not have to go
23 through all of this. And also, most air units
24 that just transiently -- it is mainly for 30-day
25 stays or longer that it will cover. That is the

1 intent of the surveillance monitoring.

2 DR. BROOME: One of the concerns of
3 the Board regarding assessment of potential
4 related syndromes after deployment has been
5 getting accurate information on troop movement.
6 And I wondered if there are any changes or could
7 you describe the system and how accurate it will
8 be for defining troop movement throughout their
9 deployment?

10 COMMANDER DEFRAITES: It is not --
11 there is not anything dictated in the plans that
12 are existing right now for the geographical piece
13 of this. But I think the one thing that is in
14 the favor of this particular deployment is that
15 most of these troop locations for the most part
16 are fairly fixed. And troops, especially the 1st
17 infantry division -- I mean fixed in a general
18 sense in that you will have a forward operating
19 base that you will keep coming back to and that
20 you will have road patrols going out and coming
21 back to the same locations. There is not going
22 to be a big end-run through Iraq and Kuwait like
23 -- well, we hope not. We hope it doesn't
24 deteriorate to that extent. There is always the
25 possibility, I guess.

1 This is just my personal opinion that
2 it is probably going to be a fairly stable type
3 environment. For pinpoint locations of troops,
4 no, we don't really have any capability right
5 now.

6 DR. ASCHER: We saw a CHPPM, and they
7 had to retrofit that enormous GIS program for the
8 smoke exposure. It would be nice if you would
9 start maybe collecting that. It wouldn't be that
10 difficult, particularly if you say it is
11 relatively stable. Particularly as we would like
12 to see if there are cases of TB or hantavirus or
13 congo crimean or typhus or whatever. We would
14 like to know where those people were. It would
15 help make a real map.

16 DR. JOSEPH: It may not be a bad idea.
17 We are not currently planning -- for those that
18 don't know what Mike is referring to, we have --
19 the Army has got a so-called geographic locator
20 study which is the data will be available early
21 this year in 1996, which will give you the
22 location of every unit for every day in the gulf.
23 Now that, as I said, is a large area and a lot
24 of people, and we are obviously going to use that
25 for the PTI issues. But this is a very different

1 setting. It is a much smaller area and the
2 locations are much more fixed and there is not
3 that much maneuver, at least as anybody can see.

4 It would be relatively easy to get somewhere
5 like perhaps with a lot less technology and cost
6 to get some clear idea of location.

7 The problem is what location means.

8 You know, if somebody is assigned to the IFOR
9 headquarters in Tuzla, but their job is driving
10 back and forth to Tazar in Hungary, then their
11 unit location is one thing, but where they
12 actually are and whether they are in the grass or
13 not is different. But I think it is a good
14 thought. We ought to look at how refined we
15 might be able to get, geographic unit or
16 individual located at them.

17 DR. ASCHER: We thought the TB
18 exercise where you have to approach everybody
19 that you are going to offer the vaccine to with a
20 form to either decline or accept the process, it
21 would be nice to write down their GIS coordinates
22 on their consent form. In other words, you could
23 capture the location of individuals through the
24 process of the TBE exercise.

25 COMMANDER DEFRAITES: On a one-time

1 basis. You will know that day where they were.

2 DR. ASCHER: Correct.

3 COMMANDER DEFRAITES: But what about
4 next week?

5 DR. ASCHER: But it would give you,
6 then, if you had really hot spots, you could line
7 them up. You might figure it out.

8 DR. JOSEPH: Well, the thrust of the
9 recommendation, in quotes, I think is a good one.
10 We will look at that.

11 DR. KULLER: Thank you very much.
12 Major Gambel, Preventive Medicine Officer at
13 Walter Reed will talk about use of personal
14 protective measures to prevent insect bites.

15 MAJOR GAMBEL: Can you turn on the
16 slide projector, please? Thank you, and turn the
17 lights down just a little. Good morning. The
18 topic of my talk this morning is the U.S.
19 military system of personal protective measures
20 to prevent insect bites, soldiers knowledge,
21 attitudes and use.

22 I have several objectives. There will
23 be at least 10 or 15 minutes at the end before
24 lunch for discussion. I will begin by describing
25 the U.S. military system of personal protective

1 measures or PPMs. Next I will describe one
2 disease outbreak investigation that recommended
3 greater attention to PPMs. And finally, I will
4 present and discuss two surveys of soldiers' PPM
5 knowledge, attitudes, and use.

6 In the early 1980's, there was
7 interest in developing a better military issue
8 insect repellent. At that time, 75 percent DEET
9 in the bottle was the U.S. military's topical and
10 clothing repellent. To obtain soldiers' input
11 into the development process, Hooper and Wirtz
12 conducted a survey of over 1,500 soldiers at 7
13 training and doctoring command installations. Key
14 findings showed that about half did not use the
15 Army's repellent. Most felt the Army's repellent
16 lasted for three hours or less. Commercial
17 products were used more often than the Army's
18 repellent, and a majority felt that the Army
19 needed a better repellent.

20 By 1991, 75 percent DEET was no longer
21 the U.S. military's topical insect repellent.
22 Joint development led to its replacement, 33
23 percent extended duration DEET lotion in the
24 tube. This new DEET lasted from 8 to 12 hours
25 and had less of the negative properties

1 identified in the survey by Hooper and Wirtz. In
2 addition, permethrin, a contact insecticide,
3 became available to treat the field battle dress
4 uniform or BDU. BDU treatment is important to
5 stop crawling arthropods such as ticks.

6 There are three ways to treat BDUs.
7 Individuals can use the aerosol can, one can per
8 set of BDUs, the IDAA or shake and bake kit, one
9 kit per set of BDUs, or two gallon sprayer.
10 Treatment using the last two methods lasts the
11 life of the BDU unless BDUs are dry cleaned. Bed
12 nets should also be treated with permethrin.
13 Finally, the BDUs should be worn properly to
14 serve as a barrier to direct contact.

15 This is a graphic representation of
16 the military system I just described. You can
17 see it shows what should be put on the skin, what
18 should be put on the BDU, and also the third part
19 it addresses wearing the BDU properly. I will be
20 referring to this system of PPMs for the
21 remainder of my talk. This system should be
22 viewed as a package working together to counter
23 the threat posed by flying and crawling
24 arthropods. Safe, effective, and relatively
25 inexpensive, this system should be used whenever

1 the risk of nuisance biting and related diseases
2 is significant. This system should still be used
3 even when vaccines or chemoprophylactic agents
4 are administered or when area pesticides have
5 been sprayed.

6 This table shows the unit cost of some
7 PPM items. For example, a tube of 33 percent
8 DEET costs approximately \$3.00, if you do the
9 math. The same tube at the military surplus
10 store ten minutes away from Walter Reed is \$1.00
11 more or approximately \$4.00 per tube. Also, the
12 least expensive method for permethrin treatment
13 of BDUs is by using the 2-gallon sprayer.
14 This method costs about \$2.00 per uniform for
15 lifetime treatment of the BDU.

16 It is important to note that the
17 repellent industry in the U.S. and worldwide
18 generates revenues in the hundreds of millions of
19 dollars annually and is very competitive. There
20 are many DEET and non-DEET containing products
21 available in the marketplace.

22 How well does the U.S. military follow
23 its PPM doctrine. One way of addressing this
24 question within the U.S. Army is to look at the
25 activities of the epidemiology consultant or

1 EPICON service. EPICON is essential
2 epidemiologic investigation service of the U.S.
3 Army. Since 1990, four formal investigations
4 have been conducted in which greater compliance
5 with PPMs was recommended.

6 I would like to discuss one of these
7 which involved U.S. Army rangers who attended the
8 two-week French Foreign Legion jungle training
9 course in French Guiana, as shown on this slide.

10

11 During this 1993 EPICON, 4 out of 51
12 rangers acquired cutaneous leishmaniasis, and the
13 lesions occurred on exposed areas. Not one of
14 the 4 cases used military issue repellant
15 products. Of 34 rangers surveyed, three quarter
16 used insect repellent and most used Off, that is
17 the repellant Off, exclusively. Seven did not
18 use repellant at all. All 34 rangers except one
19 used the bed net that was provided by the French
20 Foreign Legion. None of the bed nets were
21 treated with permethrin. The cost of medical
22 treatment for these cases was approximately
23 \$18,000.00 per patient, and on average each
24 patient lost 90 duty days.

25 While writing up our findings, it was

1 tempting to state the obvious. To prevent future
2 outbreaks, units should increase their compliance
3 with military doctrine regarding PPMs. However,
4 we were impressed that almost all the rangers
5 were highly motivated to use repellents and were
6 willing to spend their own money to purchase
7 commercial products. We thought that answers to
8 the following questions might lead to a better
9 understanding of what might be done to better
10 prevent insect bites in deployed personnel.

11 What is the level of soldiers'
12 knowledge regarding military PPM doctrine? To
13 what extent is there a preference for commercial
14 repellents and do soldiers have confidence in
15 military issue items? Are military issue
16 repellents available for use in the field? What
17 do soldiers think is the degree of their unit
18 commanders emphasis on military PPM doctrine in
19 the field?

20 To help answer these questions, two
21 surveys were conducted. One included non-
22 deployed soldiers and the other deployed
23 soldiers. The first survey entitled, "Soldiers
24 knowledge, attitudes, and practice regarding the
25 U.S. military system and PPMs", included soldiers

1 who were attending different Army courses in the
2 U.S. This cross sectional survey was given to
3 over 1,000 students attending 1 of 13 U.S. Army
4 courses at 7 locations. Soldiers attended these
5 courses from many different installations. We
6 were particularly interested in courses that had
7 three types of students based on their military
8 occupational specialty or area of concentration.

9 The three groups included soldiers who had
10 regular field experience, those in military
11 science who were trained for direct combat such
12 as infantrymen, soldiers who are likely to be
13 viewed as knowledgeable regarding PPMs, those in
14 health science, and soldiers who were involved in
15 distributing supplies or maintaining soldiers in
16 the field, those in logistics.

17 A 28-item questionnaire including
18 sections on demographics, knowledge, and
19 attitudes was developed, approved, and piloted.
20 At each survey site, a small group interview was
21 conducted to obtain more in-depth information
22 than could be expected from a pencil and paper
23 survey alone.

24 This slide shows the 7 locations where
25 the 13 courses were held. They go from your left

1 to right. It was Fort Bliss, Fort Sam in Texas,
2 Fort Benning in Georgia, Fort Bragg, North
3 Carolina, Fort Lee in Virginia, Carlisle Barracks
4 in Pennsylvania and Fort Leavenworth in Kansas.

5 This slide shows the 13 enlisted or
6 officer courses, their 7 locations, and the
7 number of participants per course. Soldiers who
8 were within the first couple of years of their
9 Army careers were not included in this survey.
10 Courses for enlisted soldiers included the
11 Professional Leadership Development Course, PLDC
12 for those with approximately 4 years in service,
13 and the advance non-commissioner officers course,
14 ANOC for those with approximately 12 years in
15 service. Courses for officers included the
16 officers advance course for those with
17 approximately 6 years in service, and the
18 commander general staff college for those with
19 approximately 12 years in service. The most
20 senior participants included students at the
21 Sergeant Majors Academy, approximately 15 years
22 in service, and the Army War College,
23 approximately 18 years in service. A hybrid
24 course in special operations at Fort Bragg is the
25 Q-course. It included both enlisted and

1 officers.

2 All students, except those attending
3 the Army War College, were required to attend a
4 briefing about their participation in the survey,
5 but no one was required to participate. The Army
6 War College had the least number of participants.

7

8 The age and rank distributions in this
9 survey are higher than those of the Army
10 population in general and reflect the military
11 experience of the students attending courses
12 selected for the survey.

13 Survey participants military
14 occupational specialties or areas of
15 concentration were grouped into 11 general
16 categories. The most frequent groupings are
17 listed. Recall that the military science
18 grouping includes combat arms, those branches of
19 the army whose members directly participate in
20 battle. The respondents were mostly male and
21 caucasian.

22 With the help of the local course
23 coordinator, an initial briefing was given. This
24 briefing occurred at the Sergeant Majors Academy
25 at Fort Bliss, Texas. Once students, in this

1 case from the PLDC course, professional
2 leadership development course, at Fort Bliss had
3 begun completing the questionnaires, I went to a
4 nearby room to meet with 4 to 6 randomly chosen
5 students from the same course to being the small
6 group interview.

7 Survey results will be shown as a
8 percentage of all survey participants. In a few
9 instances, I will comment on subgroups. To
10 begin, I will show results from 5 of the
11 knowledge items from the survey questionnaire.
12 About one third of the participants correctly
13 identified the military's topical repellent.
14 Although the military science group had the
15 highest percent correct, only one half of that
16 group answered correctly. If those who report
17 never receiving military PPM information are
18 removed, the percent correct slightly increases
19 to just over one third.

20 About one quarter identified
21 permethrin for application to the BDU. About one
22 out of 10 knew that the new DEET lasted longer
23 than the old DEET. About one third associated
24 leishmaniasis with insect bites.

25 There seemed to be little difficulty

1 in answering this item. The buddy system is
2 mainly used to check for ticks.

3 This slide shows the mean number of
4 correct knowledge items by course out of a total
5 of 15 knowledge items. Respondents from the
6 infantry school at Fort Benning and special
7 operations from Fort Bragg had the highest mean
8 number correct.

9 The most senior survey participants
10 from the Army War College and the Sergeant Majors
11 Academy correctly answered about one third of the
12 knowledge items.

13 The next 10 items from the survey
14 questionnaire focus on soldiers' attitudes and
15 practice regarding PPMs. 70 percent of the
16 respondents strongly agreed or agreed with the
17 statements shown. Almost three quarters of the
18 participants strongly disagreed or disagreed with
19 this statement suggesting that they preferred
20 using insect repellents rather than getting bit
21 by insects.

22 One quarter felt they had adequate
23 information, but nearly all other respondents
24 felt that they did not have enough information
25 about military PPM doctrine.

1 Over half of the respondents thought
2 that the military issue repellents were very or
3 somewhat effective. Almost one fifth of the
4 respondents reported not using military issue
5 repellents during the last five years.

6 Almost one half thought the commercial
7 products are better than military issue
8 repellents. Almost one quarter were uncertain,
9 and most of the remainder reported not having
10 used military issue repellents within the last
11 five years.

12 What insect repellents have survey
13 participants used in the field? They report
14 using commercial products more often than
15 military issue ones, and over half reported using
16 both types of products in the field.

17 When asked to choose only one product
18 for application in the field out of a list of 15
19 items, Off and Skin-So-Soft were preferred while
20 almost one fifth had no preference. Keep in mind
21 that Skin-So-Soft has minimal repellent
22 properties at best. There was very little
23 difference in preference reported for the old
24 versus new military issue repellent.

25 Over half of the respondents preferred

1 either a mist from a spray pump or an aerosol
2 from a spray can. Another quarter preferred a
3 cream or lotion in a tube like the new DEET. It
4 is important to remember that product packaging
5 and repellant delivery systems must meet specific
6 military specifications for field use.

7 This item addresses command emphasis.

8 Over half of the participants report never
9 having been told or telling others to use PPMs in
10 the field.

11 This survey item adjusts the
12 availability of military issue repellents in the
13 field. Military issue insect repellents were
14 reported to be available at least sometimes by
15 over three quarters of participants. 8 percent
16 said never.

17 A structured small group interview of
18 4 to 6 soldiers was conducted at each location.
19 Almost every group had a lively discussion. I
20 waited for certain themes to emerge and tried to
21 see if there was a group consensus. I also was
22 listening for the lone voice in the crowd. Some
23 of the dominant themes were, "Just use something.

24 It is better than not using anything at all."

25 Others thought the topic was interesting and they

1 never really thought about it very much before.
2 But that the people who are really responsible
3 for these issues are -- and it was always someone
4 else. Senior officers pointed to senior enlisted
5 and vice versa. Group members assumed that
6 military issue items are low bid and just not as
7 good as commercial items or other less
8 conventional methods.

9 Group participants often described
10 their units as if they each had a unique culture.

11 As expected, the more field savvy guys and gals
12 educate the newcomers, and this education
13 apparently includes PPM information that may vary
14 from military doctrine. It seems that many
15 soldiers simply prefer to use items that they
16 feel have worked well for them in the past as
17 civilians. However, their exposures to biting
18 insects may be far greater than ever before as
19 soldiers. There was little concern about side
20 effects to repellents and there was no mention of
21 the concern about possible relationships between
22 repellents and Gulf War Syndrome.

23 Finally, it was clear that group
24 participants were mostly concerned about insect
25 bites and not about bad sounding diseases that

1 seemed very distant from their experience.

2 A second survey was conducted and the
3 population of interest was deployed soldiers.

4 The survey was administered in Kuwait and Haiti.

5 I administered the survey while deployed to
6 Kuwait as part of Operation Vigilant Warrior in
7 the fall of 1994. Two preventive medicine
8 colleagues administered the survey during
9 February of 1995 while they served with the
10 multi-national force as part of Operation Uphold
11 Democracy in Haiti. The Haiti mission
12 transitioned to the U.N. one month later. I
13 administered the survey in October of 1995, while
14 I was assigned to the 86th Combat Support
15 Hospital out of Fort Campbell, Kentucky. The 86
16 CASH provided health care support for the United
17 Nations' mission in Haiti over a five-month
18 period.

19 The PPM usage survey contained
20 identical knowledge items as the earlier survey
21 of U.S. Army students. Additional questionnaire
22 items asked soldiers about their PPM use during
23 their current deployment.

24 A company-sized unit from each of the
25 larger units shown on this slide participated in

1 the PPM usage survey. The two pictures in the
2 bottom center of the slide show soldiers from
3 Fort Bragg and Fort Polk working on the
4 questionnaire.

5 In contrast to the first survey, the
6 age and ranks of participants in this survey are
7 younger, more junior, and more accurately reflect
8 the demographics of the Army. 5 percent less
9 females participated in this survey compared to
10 the previous one.

11 The most frequent military
12 occupational grouping of units that participated
13 in the PPM usage survey are highlighted in
14 yellow. In Kuwait, the participants from the
15 24th ID were mostly in the military science
16 group, those soldiers who are trained for direct
17 combat.

18 In Haiti, the 25th ID was represented
19 primarily in the military and health sciences. A
20 second unit in Haiti from the 18th Airborne Corp
21 was composed of military police. Finally,
22 soldiers from a third unit in Haiti from the 2nd
23 Army Cavalry Regiment were mostly in the military
24 sciences.

25 The next three knowledge items should

1 look familiar. Overall, about two fifths of the
2 respondents could correctly identify 33 percent
3 DEET as the U.S. military issued topical
4 repellant, and a similar overall percentage was
5 found in response to item 2. Although the
6 overall percentages were very similar, there was
7 a lot of variability among the four companies
8 from item 1 to item 2.

9 Less than half of the respondents were
10 able to correctly answer this item. In the first
11 survey I presented, 86 percent of the respondents
12 answered this question correctly.

13 Despite their performance on several
14 of the PPM knowledge items just shown, when
15 participants were asked how they felt about the
16 adequacy of their knowledge of the U.S. military
17 system PPMs, 70 percent felt they had adequate
18 knowledge.

19 Referring to item 5, over half of the
20 respondents received insect bites daily or almost
21 daily. The frequency of insect bites was
22 reported much less frequently by soldiers in
23 Kuwait, who were deployed during the fall and
24 early winter when biting pressures are less
25 compared to the other seasons of the year.

1 Responses to this item on both surveys
2 are consistent. Commercial products alone or a
3 combination of military issue and commercial
4 products are used by a larger percentage of
5 respondents than military issue repellents alone.

6 Three-fourths of the soldiers in Kuwait did not
7 use repellents. 10 percent report that they were
8 never bitten.

9 On the next item, a majority were able
10 to obtain military issue repellents while
11 deployed, but almost one-third were uncertain.

12 9 percent of soldiers reported
13 treating their BDUs prior to deployment and 26
14 percent while deployed. With those who reported
15 treating their BDUs, it is unknown if the
16 treatments were properly applied.

17 This slide shows counts of what
18 products soldiers reported bringing with them on
19 their deployment. Many soldiers brought more
20 than one brand of repellent and the most common
21 item was Off followed by military issue 33
22 percent DEET and Skin-So-Soft.

23 Command emphasis is important to make
24 things happen. Soldiers were asked how much
25 their commanders emphasized the use of insect

1 repellents in general and the U.S. military issue
2 repellents in particular. In general, half of
3 the respondents answered that the degree of their
4 commander's emphasis was some but not at all.
5 With reference to military issue repellents in
6 particular, a slightly increased percentage, 55
7 percent of all respondents, answered some but not
8 enough or not at all.

9 We have looked at survey results from
10 non-deployed and deployed soldiers. I would like
11 to briefly focus on some casualties of arthropod-
12 borne disease. Patients have been evaluated and
13 treated for leishmaniasis at Walter Reed Army
14 Medical Center since 1976. This slide shows the
15 number of leishmaniasis patients treated there
16 since 1991, when the current system of PPMs came
17 into existence. With the cooperation of the
18 WRAMC Infectious Disease Service, I have been
19 able to administer the PPM usage questionnaire
20 and interview 13 cases since 1995. The stories
21 of these soldiers and marines resemble the
22 findings of the EPICON from 1993 that I described
23 earlier. All 13 cases reported very low
24 knowledge of PPM doctrine, both individually and
25 in their units. Two weeks ago, I interviewed a

1 soldier who said that he and two other soldiers
2 were given two cans of permethrin and told to
3 spray their uniforms, which they did. Since each
4 soldier had four sets of BDUs, they were 10 cans
5 short of the needed quantity for proper
6 treatment. He also reported that his unit was
7 given both 33 percent DEET and 75 percent DEET,
8 and many members of this company bought Off out
9 of their own funds.

10 There are many factors involved in the
11 process of whether a unit properly uses PPMs. In
12 my opinion, one of the major factors relates to
13 the degree of support provided by a unit's field
14 sanitation team or FST. FSTs are a requirement
15 of each U.S. Army company-sized unit. They
16 perform a variety of field preventive medicine
17 services which include the training and
18 monitoring of PPM use. While in Haiti, members
19 of the 64st Preventive Medicine Detachment
20 Battalion I interviewed representatives from 14
21 U.S. Army company-sized units. We found that 10
22 of 14 units, or 71 percent, did not have a
23 functional FST.

24 Lack of FST readiness has been
25 identified among other U.S. Army units deployed

1 to Haiti and in other theaters. Improvements in
2 the proper use of PPMs by soldiers might go hand-
3 in-hand with improvements in unit FST readiness.

4
5 What are the main findings. Soldiers
6 do not want to get bit by insects and they will
7 spend their own money to buy products that they
8 think are effective. The level of knowledge
9 regarding U.S. military PPM doctrine appears low
10 and seems to cut across ranks and occupational
11 specialties. As identified in earlier surveys,
12 soldiers prefer commercial products. Soldiers
13 frequently do not treat their BDUs with
14 permethrin, and those that do may not be applying
15 permethrin properly. Command emphasis upon
16 military doctrine regarding PPMs appears
17 insufficient. Field sanitation teams need to
18 have trained and equipped personnel ready to
19 perform a broad range of field preventive
20 medicine activities including the support of
21 proper PPM use.

22 What can be done? Military school
23 curricula, field manuals, and other commonly used
24 reference materials must be updated to include
25 current PPM doctrine. Soldiers should be trained

1 and tested at the unit level. Common testing
2 reinforces the importance of the task and assures
3 regular testing to standard. Soldiers attitudes,
4 myths, and memories that undermine the current
5 PPM system in favor of commercial, sporadic, or
6 no repellent use should be addressed. Targeted
7 behavior approaches at the small unit level
8 beyond the standard briefing may be necessary to
9 promote change. Commanders must enforce proper
10 PPM use in the field and support fully functional
11 FSTs. For example, BDUs should be properly
12 treated with permethrin prior to deployment.
13 Periodic assessment of the state of proper PPM
14 use among all three military branches should be
15 considered. In addition, research and
16 development into more effective, safe, and user-
17 friendly PPM products as well as into better ways
18 of promoting compliance with PPM doctrine should
19 be encouraged. Finally, PPM products should be
20 tested under the operational conditions that
21 military personnel often encounter in the field.

22 I wish to thank the following people
23 who helped to make the surveys and this
24 presentation possible. That is a tick at the
25 bottom waiting for a victim. This cartoon says,

1 "You say treat BDUs before going to the field?
2 So it matters what kind of bug juice I use?
3 Well, I'll be!" If we can have the lights? Sir?

4 DR. KULLER: One question I would have
5 is what do you call the products? One of the
6 things that is obviously of interest is the fact
7 that the people who sell -- as you pointed out,
8 the people who sell the products commercially
9 make a lot of money selling the product and
10 therefore they have people who use the product.
11 But those of us who work in public health create
12 products which we can't sell. So the question is,
13 do we do something, obviously, which is not as
14 good as somebody else does? I mean, if you
15 called the product Super-Off, would more people -
16 - would the troops use it? Or would you call it
17 Super-Off Scented. I mean, just being silly, but
18 in reality is the name of the product or the
19 recognition of the products and its benefit a
20 potential problem here in terms of the use of the
21 product? Is it the fact that the name
22 recognition is a fundamental problem?

23 MAJOR GAMBEL: Well, there is no doubt
24 that packaging matters. We know that in all
25 aspects of our life. When I went and conducted

1 each of the group interviews, I took two products
2 with me. I took this product and I took this
3 product. They are the same product. I always
4 asked, which one do you prefer? And without a
5 doubt, they preferred that one. And it was very
6 interesting because in some of the units, they
7 had this product in military issue available to
8 them, but they went out and bought this product.

9 Sir?

10 DR. WOLFE: I think you've got a very
11 good product there in your 33 percent cream. It
12 is effective. It is much safer than the 75
13 percent. And perhaps most importantly, it has a
14 longer duration of action with the stabilizer
15 that is in it. That colored package that you
16 showed on the commercial market is called
17 Ultrascreen made by 3-M. I understand that it is
18 either in short supply or that they may stop
19 making it, which is very unfortunate because it
20 is what I recommend to people who are traveling
21 for the reasons that I stated. I think if you
22 can emphasize these very important effective
23 factors of this product, even though it is in
24 military issue green, you might be able to change
25 the attitudes of these people about going out and

1 buying commercial products. I would also
2 recommend that you take the 75 percent solution
3 or cream out of your supply and stop giving
4 people the choice between the two. Because the
5 75 percent has the potential for toxicity and
6 does not have a stabilizer. It may be more
7 effective when you've got excessive amounts of
8 insects and people who go up to Canada to fish in
9 the summer because of the black flies use the
10 strongest solution available, 95 percent or so,
11 but for your needs -- military needs -- the 33
12 percent should be adequate.

13 MAJOR GAMBEL: Yes, sir?

14 DR. GWALTNEY: You might be interested
15 in a different perspective. I compete in
16 retriever field trials and we go to bad places
17 like Lakehurst Naval Air Station, where I once
18 got 114 chigger bites and I must have had 50
19 ticks on me. I have been at field trials where
20 somebody shows up with military issue repellents
21 and the people line up to get this stuff. They
22 leave their Off in the car and they say this is
23 really good stuff. This is really strong. This
24 is the military. Exactly the opposite
25 perception. They don't know any more whether it

1 works or not than the troops do compared to Off,
2 but it is exactly the opposite perception.

3 MAJOR GAMBEL: That is good to hear.
4 I think one of the take-home messages is that if
5 soldiers, especially on the line, are going to
6 start using the 33 percent DEET and treat their
7 BDUs with permethrin prior to deployment that
8 their leadership, both on the officer and
9 enlisted side, need to be educated and lead in
10 that effort.

11 DR. ASCHER: That may be the reason
12 that civilians want machine guns. They are more
13 effective. The issue of tick-borne diseases has
14 a couple of -- I won't say paradoxes, but a
15 couple of twists in it that we considered in our
16 TB discussion. Four illnesses in the deployment
17 that our folks will get from ticks possibly:
18 Rickettsia conari, Congo-Crimean, Lyme disease,
19 and tick-borne encephalitis. They all have
20 different ticks. They all have different tick
21 biology. They all have different tick life
22 cycle. They all have different tick attachment.

23

24 So one of the problems is, as an
25 example of Lyme, if it is transmitted by the

1 nymphs, how many people have ever found a nympha
2 tick. If you get a big tick, you notice it. So
3 a lot of the transmission is really not of a type
4 that you would even know you had ticks. And in
5 the case of TBE, we put all these variables
6 together and came up with the fact that it is
7 carried by all phases of ticks and the attachment
8 time for transmission is very short. So we are
9 sort of saying if any of these four diseases was
10 to break through a personal protection, it would
11 be TBE. It was on that far end of the spectrum.

12 Whereas Rickettsia conari with the bigger tick
13 and more obvious exposure might be more easily
14 presented. So, I don't know. I think you will
15 have Lyme as another marker in this population to
16 see in their post-deployment sera how many are
17 inapparently affected by Lyme, Rickettsia, and
18 everything else. They did this at Fort Chaffee,
19 as you well know.

20 MAJOR GAMBEL: Sure.

21 DR. ASCHER: And there is a fair
22 amount of inapparent infection and you might be
23 able to correlate it back in terms of whether
24 people were doing their thing or not.

25 MAJOR GAMBEL: I wonder in Bosnia if

1 company-sized units, at least with the U.S. Army,
2 have field sanitation teams that are functional?

3 Because in Haiti, when we were going around we
4 asked and virtually every company said yes, and
5 they can show you a list of field sanitation team
6 members, but then when you asked to find out have
7 they attended the 40-hour field sanitation team
8 class, do they have equipment, do they have
9 supplies, do you have any records of what you
10 have been doing, they were invisible.

11 DR. BROOME: Did you look at your data
12 --if you had any with functional field sanitation
13 teams, could you tell any difference in the use
14 of PPMs in the companies with functional FSTs
15 compared to those without?

16 MAJOR GAMBEL: I really couldn't -- I
17 can't answer that question. I couldn't find any
18 difference.

19 DR. BROOME: Well, I mean does that
20 mean that none of them were functional or there
21 was no difference in use of PPM?

22 MAJOR GAMBEL: There was no difference
23 in the use of PPMs among the groups that we
24 looked at?

25 DR. BROOME: Did some of them have

1 functional FSTs?

2 MAJOR GAMBEL: There was -- I report
3 71 percent did not. I will tell you that the
4 ones that I am saying are functional, I think
5 that some of my environmental science officer
6 colleagues would suggest that they were barely
7 functional at best.

8 DR. BROOME: I guess my point is that
9 you may well be right, but I can also postulate
10 that people don't necessarily listen to their FST
11 and that you could invest a lot of energy into
12 FSTs without getting your desired result.

13 MAJOR GAMBEL: I agree.

14 DR. BROOME: So I think your studies
15 are very interesting, but I would also look at
16 cross tabs of insect bites by use of PPM.
17 Further analysis of your own data to see whether
18 you can make a case for something that will help
19 you with education and something that will help
20 you with policy decisions.

21 DR. ASCHER: On the same -- we also
22 got a very mixed response to our recommendation
23 about the rodent control issue from the same
24 perspective. In other words, people said it is
25 impossible to control rodents even if you had the

1 teams. Other people said there are no teams. We
2 don't quite know what the answer is and maybe we
3 should ask the question of the folks here as to
4 what do they really think is going to be
5 happening in the field in Bosnia in terms of the
6 side issue or the second issue of rodent control,
7 vis a vis hantavirus. That is a different issue.

8 That is a field sanitation team that really does
9 something rather than educate. That is a second.

10 Do you think there is going to be any effective
11 rodent control in the field?

12 MAJOR GAMBEL: I am not that familiar
13 with the teams that are deployed to Bosnia, but I
14 would imagine that if the field sanitation teams
15 are not trained up and don't have the equipment
16 and are not engaged, then we won't even have an
17 opportunity to find out if they would be
18 effective.

19 CAPTAIN CUNNION: Steve Cunnion. Did
20 you correlate the use of different repellents and
21 the reported insect bites?

22 MAJOR GAMBEL: No, sir. Not yet.

23 CAPTAIN CUNNION: Marty, about the 75
24 percent, that is used mostly to keep fires going
25 in the rain because there is a lot of alcohol in

1 it.

2 MAJOR GAMBEL: Actually, there is a
3 use for the 75 percent DEET and there is a reason
4 why it is still in our arsenal, and that is for
5 military police that have a vest that they are on
6 duty at night. They are under lights attracting
7 lots of insects and arthropods and they are
8 supposed to soak this outside vest that fits over
9 their blouse in 75 percent DEET and it is very
10 effective in helping our military police.
11 Otherwise, in a lot of these situations they
12 would have to wear a head net and that would
13 decrease their visibility.

14 CAPTAIN CUNNION: The DEET jacket that
15 you are referring to is much more than just
16 military police. It is any static defense
17 position.

18 MAJOR GAMBEL: Yes.

19 CAPTAIN CUNNION: The other thing --
20 the problem with the permethrin uniforms, I
21 think, is that we are putting the responsibility
22 on the individual soldier. I think we need to
23 move that up to either company or battalion
24 level. I know at least with the desert uniforms,
25 we are doing it at the factory, figuring out that

1 nobody will be wearing a desert BDU unless he was
2 in the desert, whereas the green fatigues are
3 used commonly as garrison uniforms. But I think
4 it should be the company or the battalion's
5 responsibility to group treat all uniforms when
6 people go to the field, not leave it up to the
7 individual soldier.

8 DR. POLAND: What type of missions
9 preclude the use of PPM? There is a statement in
10 the TBE draft that says that while we maybe would
11 use the vaccine in people whose missions preclude
12 the use of PPMs. What would those be?

13 MAJOR GAMBEL: Well, I didn't write
14 that policy. I am not sure what they were
15 thinking of.

16 DR. JOSEPH: There are special
17 operations functions that preclude the use of
18 PPM-treated uniforms.

19 DR. POLAND: There is no other real
20 reason why they can't use the uniforms then? I
21 don't mean those individuals. But what about
22 people that have skin allergies, for example?

23 MAJOR GAMBEL: Yes. There are some
24 people who are probably sensitive to DEET and
25 permethrin and they should not be using these.

1 DR. POLAND: What is their option
2 then?

3 MAJOR GAMBEL: We don't have very good
4 options except proper wearing of the uniform.

5 COMMANDER PARKINSON: One of the
6 comments you make at the end of your talk, which
7 is right on, is looking across the other
8 services. And I can tell you that Colonel
9 Cropper, one of our public health officers,
10 looked at this issue and the same level of
11 understanding and compliance exists in the Air
12 Force among people who deploy unfortunately. And
13 as we have been talking more and more about this
14 issue, our traditional approach to preventive
15 medicine education is the squadron pre-deployment
16 briefing type of thing where a public health
17 officer kind of gets up and talks to them in an
18 ongoing fashion. And really the more I think
19 about it and talk amongst our folks is that when
20 we look at who gets malaria and who gets these
21 diseases, it is security policemen and special
22 ops types. It is not the air crews that do it.
23 And what we have got to better do is get into the
24 guts of the mainstream training of our SPs as
25 they get into that initial tech school and get

1 into that curriculum rather than get them out the
2 other end and talk about it just before they are
3 ready to go on a deployment. So I think the
4 whole way we do this has got to be
5 reinvestigated.

6 The other thing is the issue of
7 special ops. I don't know if you had special ops
8 people there, but our people say, well, you can
9 smell it and you can detect it, and yet the very
10 highest risk people that need it are the ones --
11 and I am not sure how well this aura and culture
12 inside a unit -- and that special ops culture is
13 very special and very few people have access to
14 it regularly, and I think maybe we need to do a
15 little more work. I am talking Air Force now
16 because of all these things about it. Whatever.
17 Maybe yes or maybe no. I don't know.

18 MAJOR GAMBEL: Yes.

19 COM. SHARP: To amplify something, the
20 first thing Mike said. I recently reviewed the
21 Marine Corps' books. They are the essential task
22 books. As you progress up through the Marine
23 Corps, these books define everything you are
24 supposed to know to be a Marine. And there is
25 nothing -- there is very little medical in there

1 and there is certainly nothing in there at all
2 about how to use personal protective measures.
3 And it seems, as I guess Mike was saying, is that
4 the way it gets taught then is that when troops
5 go into the field they either get a crash course
6 in it or somebody tries to tell them out in the
7 field. One, I think, very effective way to deal
8 with this would be to make this an essential task
9 and then Marines would learn it right from the
10 beginning. They would be tested on it and so
11 forth.

12 MAJOR GAMBEL: There is some momentum
13 for that for a common task testing coming out of
14 the MEDCOM for the Army in San Antonio, but it
15 will probably be a year or two before that
16 actually gets incorporated.

17 I just want to add that while doing
18 the group interviews, it was the most enjoyable
19 part for me, and there really is a lot of feeling
20 out there among, I think, our soldiers about this
21 issue. When at Fort Benning and doing the group
22 interview with the captains at the officers
23 advance course, there were several of them that
24 were extremely angry because they had just
25 finished 6 hours of the required health subjects

1 and they walked away and two of them said to me,
2 we just spent 6 hours and there is nothing that I
3 can use here. There is nothing I can use. And by
4 accident you have come down and you just happen
5 to be talking about this. This is something that
6 I can give my soldiers that can help protect them
7 in the field, and that impressed me. So I wanted
8 to share that with you.

9 DR. JOSEPH: Why do you think that is?

10 I mean a lot of people have said in very
11 different ways that either as a point of basic
12 military training or pre-deployment or whatever
13 that the education is either absent or
14 ineffective. Why do you think that is in this
15 particular area especially?

16 MAJOR GAMBEL: I think it requires
17 people to --

18 DR. JOSEPH: Excuse me. It is very
19 counter-intuitive because nobody likes to be bit
20 by bugs and most everybody understands that bugs
21 are a hazard, a significant disease hazard to
22 deployed troops. And everything -- all your data
23 move in the opposite direction. Why do you think
24 that is?

25 MAJOR GAMBEL: Well, I think there is

1 a well-entrenched attitude against use of insect
2 repellant. It is asking people to do something
3 that doesn't really feel that good. It is asking
4 people to put on a repellant, even the 33 percent
5 DEET, when they are not getting bit. Because we
6 want them to put it on before they get bit. And
7 even though it lasts 8 to 12 hours, it is still
8 somewhat thick. And for people who are in
9 operational environments that have lots of other
10 responsibilities and activities, the last thing
11 they are thinking about is putting on their
12 repellant.

13 This problem goes way back. I
14 actually have a slide or an excerpt from the PM
15 books accounting for the situations in World War
16 II. This paragraph -- we don't need to show it,
17 I guess -- but it talks about how nurses during
18 World War II refused to use insect repellant, but
19 the same nurses would go to the beaches and put
20 on gobs of suntan lotion.

21 DR. JOSEPH: My question was a little
22 different. It wasn't so much about why people
23 refuse to self-administer the repellant. It was
24 why the training and doctrine seems either absent
25 or ineffective?

1 CAPTAIN CUNNION: Sir, there is
2 unfortunately a long-term tradition of separating
3 military from medicine. It is what he found out
4 in his interviews that somebody else is
5 responsible. So the line says medical is
6 responsible and medical says the line is
7 responsible and nothing happens.

8 COMMANDER PARKINSON: Well, I think
9 even beyond that you said that there is a culture
10 to units. And I can say in the Air Force, there
11 is a culture to training command which does
12 training. Which means that we control the
13 training and you come to us on hands and knees
14 and argue about why you need any of our time to
15 talk about things that really aren't our stuff
16 like insect repellents or personal protection
17 measures. And we have worked very hard over
18 several years to get longer blocks of time in
19 basic recruit training. And now what we are
20 talking about is getting into the tech schools.
21 Because as they come out of that recruit
22 training, they are getting a narrower and
23 narrower identification group where they get
24 their social and educational norms form. So now
25 what we have got to do is get to the tech

1 schools. The measure of a good SP is the way to
2 which he uses his PPMs. But in order for me to
3 get in that gate, I have got to get a high-level
4 person to engage a three star general who owns
5 that curriculum. It is the reason that General
6 Roadman recently has fought for and established a
7 medical chair at Air University and designated
8 six slots to get the medics in the guts of the
9 line. Because he said the line people just are
10 not hearing the medical view unless we own some
11 piece of their curriculum and staff position.

12 DR. JOSEPH: I suggest it is more
13 complicated than that. I don't want to take up
14 too much time.

15 DR. KULLER: No. It is very
16 interesting. Go ahead.

17 DR. JOSEPH: In the very recent past,
18 I have talked to the CINC and the DCINC at EUCOM,
19 General Abrams and his entire flag staff, and I
20 assure you that they are very aware -- extremely
21 aware of the importance of this issue of personal
22 protection. So I think we are getting ourselves
23 off a little too easy when we say it is back up
24 there with General Slim and Field Marshall
25 Rommel. I think the issue is more complicated

1 than that.

2 MAJOR GAMBEL: I agree.

3 DR. JOSEPH: My guess is that it is
4 with the captains. My guess is that it is with
5 the unit leadership rather than the highest
6 level.

7 COMMANDER PARKINSON: But the way we
8 get to that, sir, is by building in the
9 expectation that that is a component of unit
10 leadership that we are going to hold you
11 accountable for. And that is where, in order to
12 get into that mainstream of officership and NCO-
13 ship --

14 DR. JOSEPH: Well, now you are
15 beginning to approach something that I think is a
16 more useful kind of approach.

17 CAPTAIN CUNNION: Well, like smoking
18 cessation. To get smoking cessation in the Navy
19 training program, the only thing we could get was
20 15 second spots in the training program. They
21 wouldn't give us any time for smoking cessation.
22 That is all we got was these little commercials
23 that we made of 15 seconds. Because they are so
24 crowded in the training time that you've got to
25 prove to them, just like what Mike was saying,

1 that you are a higher priority than all of the
2 rest of the training. And what we have done in
3 the military in the last 20 years is cut down on
4 training time. The time that a corpsman gets
5 trained in the Navy now is one half of what was
6 done during the Vietnam era. We are just
7 crunching our training down.

8 When we cut budgets, usually the part
9 of the budget that gets cut is training. So
10 everything gets shrunk. Our basic training gets
11 shrunk and every one of the courses gets shrunk.

12

13 COLONEL BRUNDAGE: I think that what
14 you have talked about, Jeff, is something that I
15 think a lot of us have noticed. And that is that
16 the leaders of the Army, for instance, are -- it
17 is not a problem that they are not motivated. It
18 is not a problem that they are not smart. So why
19 don't they know about these things and why don't
20 they enforce them and make their FSTs and their
21 people do these things. If you look at the
22 military education process that starts with OCS
23 and West Point and the basic course and the
24 advanced course and the command and general staff
25 and the War College, and you say in all of that

1 training that tells these highly motivated, smart
2 people the things that they need to do to fight
3 and win wars, how much of this has to do with
4 care and maintenance of the M-1, A-1, OD, and
5 color one each Joe, GI?

6 The answer to that is very little.
7 They learn all kinds of things about care and
8 maintenance of weapons and vehicles and
9 equipment. They take that very, very seriously.

10 There is no problem getting on the curriculum to
11 do a first echelon technical inspection of a
12 vehicle because they have been told from the
13 first day that they started becoming an officer
14 or an NCO that this is important to being
15 successful as a professional soldier.

16 And I think the problem is what we
17 have talked about. That is, we have convinced
18 the line army that everything medical we will do.

19 We will train the field sanitation teams. We
20 will put the permethrin and the DEET and all of
21 that stuff out there and you don't have to worry
22 about it. The problem is that for first echelon
23 maintenance, of soldiers, that is a command
24 responsibility. And it seems to me that it will
25 take at least a generation, if we start today and

1 are very successful, to change the whole culture
2 of that. So that commanders and NCOs don't have
3 to be told this is important, but they learn or
4 are inculturated with the importance of
5 maintaining soldiers and using PPMs as part of
6 that. It is just like if you break a jeep
7 because you didn't check the oil, the commander
8 gets in a lot of trouble for that. Commanders
9 don't get in trouble if they have a soldier who
10 gets admitted to WRAMC and is treated for
11 leishmaniasis. They get a replacement.

12 So it is interesting. I have been in
13 this room, like many of us, for 15 years and have
14 heard the same conversation go on almost the same
15 way, and we always end up saying those darn
16 commanders, those darn FST guys, those darn
17 TRADOC people. We all go, we eat lunch, and
18 nothing happens. And I think it is because it is
19 not a quick fix and it is not an easy fix. It is
20 something that is very, very difficult and it is
21 going to take 20 years before this problem is
22 completely resolved, if we start today.

23 DR. KULLER: I think we have to break.

24 But I would suggest two important things here.

25 One, the whole basis of prevention of disease in

1 Bosnia is based on personal preventive measures.

2 So it seems to me it is crucial that we have
3 more careful monitoring, as you've done here, to
4 find out exactly what is going on. And two, that
5 major efforts be made to maximize the response.
6 Otherwise, we have a proposed plan of prevention
7 which is clearly not going to work because it is
8 based on something which hasn't worked in the
9 past.

10 The second thing I would suggest, and
11 this again is maybe a little facetious, but it
12 basically is to approach the companies in the
13 commercial world that have the largest market
14 share of success in selling these products and
15 ask them perhaps or in some way to say how can we
16 get it used properly. I mean, we have done this
17 a couple of times and have been amazed at the
18 change in the response to various preventive
19 activities which have been generated by people
20 who are in this business because they are making
21 a living doing this. If their product doesn't
22 sell, they are out of business. And what you are
23 trying to do is sell a product. And I would tend
24 to agree with you in the sense that we go around
25 in circles on this. But the reality is, you are

1 trying to sell a product and we are kind of
2 amateurish at this. And it may just turn out,
3 silly as it may seem, that you've got to change
4 the color of the container.

5 But I think the other point is that it
6 is absolutely crucial to use an environmental
7 approach to dealing with the clothing. I think
8 to depend on each soldier to do that would be a
9 dreadful mistake. And I think there is a
10 potential that you certainly could do
11 immediately, and that is to make sure that
12 basically this is done as an environmental
13 approach, that is, at the company level so that
14 the soldier gets a uniform which is already
15 impregnated and gets a bed net that is already
16 impregnated, and he doesn't have to deal with
17 that issue. At least then you are dealing only
18 with local use of DEET, and there again it is a
19 question of how do you advertise it and how do
20 you get people to use it. And I think the best
21 thing to do would be to look at people in the
22 behavioral area or best in the advertising area
23 and say how do I sell my product. I think we
24 have to take a break first.

25 COLONEL FOGELMAN: I have several

1 announcements before you break. As far as lunch,
2 there are several snack bars and cafeterias here
3 on post. There is one in the main hospital on
4 the third floor, which is -- I don't know where
5 the front of the building is, but from the front
6 it is over that way. There is also a snack bar
7 in the old hospital, which is Building 1 on the
8 first floor. There is an NCO club at the bottom
9 of the hill from Building 40 which has an
10 oriental cafeteria. There are also some vending
11 machines in the basement for those that need just
12 a quick lunch, and Colonel Takafuji has offered
13 his office for any AFEB members that want to eat
14 there. Also, if the board members could meet
15 outside the south door, which is the door
16 opposite the front door that you came in on for a
17 few minutes for a picture, we would appreciate
18 it. And the north side door, the main door, that
19 you came in is temporarily being closed for
20 repairs. So you need to go out the side doors
21 for lunch. We need to come back by 1:30, please -
22 - 1330.

23 (Whereupon, at 12:00 p.m. the meeting
24 was adjourned for lunch to reconvene this same
25 day at 1:30 p.m.)

1 So I thought that perhaps this would be of use
2 to particularly the Marines in Okinawa, but also
3 any of the Armed Forces that deploy to field
4 conditions in Asia or the Pacific.

5 I would like to give a little bit of
6 background. I know that the members of the board
7 are familiar with the disease, but we do have
8 some people in the audience that may not be as
9 familiar. Japanese encephalitis is a very
10 serious infection in some people. It is common
11 throughout Asia, or through many parts of Asia.
12 Most people who get infected don't get sick.
13 They perhaps have a mild flu-like illness and
14 recover. But of the 1 to 5 percent who do become
15 clinically ill, they become extremely ill. They
16 can go into a coma. 25 percent of them don't
17 survive the illness. 50 of them that do survive
18 survive with permanent neuropsychiatric deficits.

19

20 The best estimates are that there are
21 about 50,000 cases worldwide. It is caused by a
22 virus, a flavivirus, and it is transmitted by
23 mosquitos. The mosquitos don't like to bite
24 humans as their first choice of meals, but they
25 will bite humans if they happen to be around. It

1 causes an asymptomatic infection in pigs and in
2 wild water fowl, and then if people are camped
3 out at night when the mosquitos are biting near
4 these pigs, then they can be accidentally
5 infected. In Okinawa, it is a seasonal illness
6 that is primarily transmitted in the months of
7 April through October.

8 That is a map of the distribution and
9 effects. Almost all of Asia and part of India as
10 well. It wouldn't be such a problem, but the
11 pigs are able to tolerate very high loads of
12 viremia and the more there is, the more mosquitos
13 are infected. They say that 100 percent of the
14 pigs in Okinawa have got the virus. So any
15 marines that happen to be camping near pig farms
16 are at risk.

17 The experience in the U.S. military, I
18 don't have precise numbers from World War II, the
19 Korean War, and Vietnam, but since 1986 there
20 have been six documented cases in U.S. military
21 personnel and two more in their dependent
22 beneficiaries. In 1991 were the last cases,
23 three cases in Marines in Okinawa. No fatalities
24 but serious neurological consequences for some of
25 these Marines.

1 When they did sero surveys to find out
2 whether or not there is asymptomatic infections,
3 they found out that 10 percent of the Marines on
4 Okinawa were already sero positive.

5 So to combat this problem, the
6 Japanese encephalitis vaccine was recommended.
7 After a lot of testing by primarily the U.S.
8 military, the Food and Drug Administration
9 licensed the vaccine in December of 1992. It is
10 used in Japan as a two-dose series, but it was
11 found to not give sufficient protective titers
12 for American personnel, and there is a three-dose
13 vaccine series that is recommended for U.S.
14 personnel. It is the way the package insert
15 reads -- get the three-dose series.

16 The Navy and Marine Corps'
17 recommendations for Japanese encephalitis vaccine
18 is that it should be given to all personnel who
19 are subject to short-notice rapid deployment to
20 field conditions in Asia. And that primarily
21 means Marines and Sea Bees. FMF, Fleet Marine
22 Force, rather, are Navy personnel who are
23 assigned to Marines. Marines don't have all the
24 same specialties within the Marine Corps that the
25 Navy does, so the Navy does a lot of support.

1 The Sea Bees, Navy Mobile Construction Battalion
2 personnel, are people that go out there where
3 there is nothing. They live in field conditions
4 until they build something better. And all
5 special operations personnel. But it doesn't
6 usually include people who are on ships. People
7 in the hospital in Okinawa don't have to have
8 this vaccine. It is people who are going to be
9 in field conditions at night in rural areas.

10 Currently, the Japanese encephalitis
11 booster recommendations are from the ACIP
12 published in MMWR in 1993, and it says that
13 although the duration of protection is unknown,
14 they can't give definitive recommendations on
15 just what the timing for booster doses should be,
16 but they may be administered after two years.
17 And the package insert looks like they took this
18 ACIP recommendation and just reworded it and said
19 that a booster dose may be given after two years,
20 but a definite recommendation can't be made on
21 spacing it beyond two years.

22 The health information for travelers,
23 the yellow book, says that you can give one dose
24 after or equal to 36 months, but definitive
25 recommendations cannot be given, and it doesn't

1 have a reference for where they got the 36
2 months. The joint immunization instruction, the
3 one that just came out in November of 1995 for
4 the Army, Air Force, Navy, and Coast Guard says
5 that when it comes to Japanese encephalitis, the
6 schedule of immunization is provided by the
7 Services. And the last guidance that the Navy
8 came out with for the Navy and Marine Corps is
9 dated April of 1993, and it says that personnel
10 who require Japanese encephalitis vaccine must
11 receive the booster doses in accordance with --
12 and then to paraphrase it, the recommendations in
13 the package insert which says they cannot give
14 definitive recommendations beyond the 2-year
15 interval.

16 But the study published in Journals of
17 Infectious Disease was entitled "Japanese
18 encephalitis, persistence of antibody up to 3
19 years after a three-dose primary series",
20 discusses a study that was done by people at
21 Walter Reed Army Institute of Research. They had
22 286 soldiers who were vaccinated with the 3-dose
23 series in 1990, and 3 years later they had serum
24 from 39 of those individuals. And of these 39
25 individuals, they were able to get in touch with

1 and do phone interviews with 26 of them. The
2 serum was tested for virus neutralizing antibody
3 using the enhanced plaque reduction
4 neutralization test, and when the titers are
5 greater than 1:10, it is considered protective.
6 So in this study, starting with 286, of the 39
7 individuals tested 3 years later, 95 percent of
8 them had protective antibodies. When they
9 interviewed those 26 people, they tried to decide
10 whether some of them had gotten the booster after
11 2 years or some other reason there was a booster,
12 and they tried to separate those out. I call
13 that endemic travel. But travel in Asia was
14 considered to have been potentially a boosting
15 effect. So of the 17 people that were
16 interviewed who had not had either a booster
17 immunization or traveled to an endemic area, 94
18 percent of them or 16 out of the 17 still had
19 protective titers three years later.

20 Of the one sample of 39 where 37 of
21 them, 95 percent of them, had protective titers,
22 the G mean titer was 127 with a confidence
23 interval way above 10. And for the vaccinees,
24 the 17 who had not gotten a booster or had
25 endemic travel, it was still way up there, 141,

1 very protected. I'm sorry, I was reading the
2 wrong column -- but 93 and 105, certainly well
3 above the 1:10.

4 I tried to get estimates of just what
5 the impact of extending the booster vaccine
6 interval would be, and I wasn't able to get good
7 numbers from the manufacturer or the supply depot
8 on how much Japanese vaccine is being utilized
9 right now. But one of my preventive medicine
10 colleagues with the Marines estimated for me that
11 a 3-year booster interval instead of 2 years
12 would save about 10,000 doses a year. That
13 10,000 doses would save about \$330,000.00.
14 Judging from what the rates of severe adverse
15 reactions are, there would be about 10 fewer
16 adverse reactions every year, one less
17 hospitalization, and of course the administrative
18 costs of not having to give 10,000 more
19 immunizations would be substantial.

20 So my questions to the board -- you've
21 got an official copy, but to paraphrase -- is
22 this evidence, even though the sample is 39, is
23 this sufficient evidence to support a
24 recommendation for U.S. military personnel to
25 extend the booster interval to 3 years instead of

1 2? And if it is, do you think that this type of
2 study would work? Should we collect more data so
3 that we can think about extending it beyond 3
4 years? And as just kind of a corollary, do you
5 have any other recommendations about what kind of
6 methodology we ought to be using to look at how
7 long to extend the booster interval? Yes?

8 DR. BROOME: Were the lab tests for
9 the six-month and the three-year done in the same
10 lab run? And if not, what is the variability in
11 the assay?

12 COMMANDER MAY: I am glad you asked
13 that question.

14 COMMANDER DEFRAITES: They were done
15 in the same lab run. They were paired up and
16 repeated -- sort of run together. The six-month
17 and the three-year were paired up.

18 COMMANDER MAY: Yes.

19 DR. POLAND: Do dependents on Okinawa
20 get the vaccine

21 COMMANDER MAY: It is not a routine
22 immunization for dependents. Certain dependents,
23 if they are at risk, they go in and tell the
24 physician that, yes, we camp out at night because
25 we are in the boy scouts. Then they could get

1 the immunization. But it is not required of
2 dependents who move with their families to
3 Okinawa. I am not certain the numbers of
4 dependents this would effect, but certainly it
5 would effect some.

6 DR. KULLER: What is the turnover on
7 Okinawa in terms of the Marines coming and going?
8 If you moved it to three years --

9 COMMANDER MAY: That depends on how
10 many Marines are on Okinawa right now?

11 CAPTAIN THOMAS: There are about
12 20,000 Marines on Okinawa. About three-quarters
13 of them are on a one-year tour. This would have
14 no effect on making the vaccine more available to
15 people who need it. So this is more Marine
16 Corps-wide and service-side. It would be less of
17 an administrative burden. The other issue that
18 we have to deal with with the Marine Corps is the
19 Marine Corps every year loses about 25 percent of
20 their total strength, about 40,000 Marines leave
21 the service every year. So this is a significant
22 number of folks. The issue here is primarily
23 administrative.

24 If I could go back also to the issue
25 of dependents. It is all dependent on where you

1 live. And a number of family members do receive
2 this vaccine. Those folks are there for 3 years,
3 and this would have a significant impact on the
4 number of vaccines we give in the Okinawa areas
5 who live adjacent to the pig farming. Pigs are
6 the primary meat source on Okinawa. There are
7 330,000 registered pigs. God knows how many
8 unregistered pigs are out marauding around. But
9 this is a significant issue in the rural areas.
10 And a number of our housing areas on Okinawa are
11 directly adjacent to the highest risk areas.

12 DR. ASCHER: I thought our previous
13 recommendation was a little stronger for
14 dependents, but I will have to go back and read
15 it.

16 COMMANDER MAY: Yes, it was stronger.

17 DR. ASCHER: Oh, okay. You are saying
18 what is happening is not quite as strong. The
19 MMWR, if I read this last paragraph, says that
20 the follow-up beyond 2 years was pending and one
21 Japanese study showed a persistence of 3 years.
22 So it opened the door for the MMWR saying that on
23 the basis of later results they would reconsider,
24 and that is what you are asking us.

25 COMMANDER MAY: That is right. I am

1 hoping that by asking the AFEB the question, we
2 can start saving the -- reaping the potential
3 benefits of this change in policy right away. It
4 is about time for people who are anticipating
5 being exposed in the peak transmission period to
6 start receiving their vaccinations and boosters.

7

8 DR. ASCHER: I am wondering -- Marty,
9 you deal with this every day. Do you want to
10 offer any kind of thoughts?

11 DR. WOLFE: Well, it is an unusual
12 person who is going to be in an endemic area for
13 two years or more. Certainly in travelers who
14 get into some very exotic places, many of them
15 have less than a month exposure, which is not
16 always a criteria for getting the vaccine. So
17 that the issue of boosters doesn't come up too
18 much.

19 CAPTAIN BERG: Bill Berg from NEHAC.
20 I would just like to point out that it is not
21 just the Marines on Okinawa who may be there
22 three years. There are large numbers of Marines
23 on the west coast of California, in particular,
24 who repeatedly rotate into Thailand or Okinawa or
25 Japan for six months. If they have a 3-year

1 assignment at Camp Pendleton, they may go over
2 twice during the course of 3 years, perhaps more
3 often. So it is not just Okinawa.

4 COLONEL HOKE: I am Charles Hoke. I
5 was responsible for the efficacy trial that was
6 done at Thailand. A large amount of the
7 serologic data that you were talking about was
8 done by Bob Defraites and Jeff Gambel. We have a
9 slide, if you wouldn't mind.

10 COMMANDER MAY: No, I wouldn't mind.

11 COLONEL HOKE: It shows the curve and
12 the time course, since time course is the issue.
13 The data were a little confusing in the paper,
14 and I thought Jeff might just describe for you
15 exactly what he did and you might want to see
16 what you might want to recommend for the further
17 time.

18 COLONEL FOGELMAN: Could you take the
19 microphone please?

20 COLONEL HOKE: Sure.

21 COLONEL FOGELMAN: Thank you.

22 MAJOR GAMBEL: I think you very well
23 described what was in our letter in JID. I think
24 for purposes here we want to point towards the
25 sero-conversion line that is horizontally going

1 across the screen. We are really just talking
2 about these two data points right here at 24 and
3 36 months. I guess the only thing that I can add
4 really is that based on the curve there, we would
5 expect that there would be protective antibody
6 beyond 36 months. That is really what I want to
7 add at this point. I don't think we really have
8 much to add in terms of the boosting. All these
9 other two lines have to do with the original
10 series and boosting at one year, which is not
11 relevant to this discussion.

12 COMMANDER MAY: Thank you very much.

13 DR. BROOME: To me it is really not a
14 cost issue as much as this is a vaccine where the
15 adverse reactions have been a real concern. And
16 the ones that you are seeing and describing, have
17 they been primarily the sort of urticarial
18 response?

19 COMMANDER MAY: Yes, they have. Isn't
20 that right, Dr. Berg?

21 CAPTAIN BERG: Yes.

22 COMMANDER MAY: Right. I knew that
23 saving money alone was not going to sway everyone
24 on the board's opinion, but certainly it reduces
25 the amount of adverse reactions you have to

1 vaccine if you give less vaccine.

2 DR. BROOME: Right. And some of those
3 urticarial reactions have been life-threatening
4 in travelers, so that this is not just your
5 average sore arm or fever. We are talking about
6 something that can potentially be serious.

7 COMMANDER MAY: Yes. It is a vaccine
8 associated with serious side effects in some
9 individuals. Yes?

10 COMMANDER DEFRAITES: This is Bob
11 Defraites. I am a little confused about the
12 rates of the adverse effects. I don't think
13 anybody knows what the rates are in boosting. I
14 think the highest rates of adverse effect were in
15 the first dose. Is that -- and then with
16 subsequent doses the rate goes down? So I am not
17 sure we will save that many adverse effects from
18 just boosting.

19 COMMANDER MAY: You are right. There
20 is limited data. I was extrapolating from the
21 data that was available.

22 CAPTAIN BERG: Bill Berg, again. The
23 study that we did on Okinawa, the rates were
24 something -- and I am pulling the figures off the
25 top of my head, so please don't hold me to them,

1 but they were something like 18 per 10,000 for
2 the first dose and about 15 per 10,000 for the
3 second dose, and then about 2 per 10,000 for the
4 third dose. Nobody has any idea what the
5 mechanism of this reaction is. The fact that a
6 large number reacted within 48 hours to the first
7 dose suggest that this may not be immunologically
8 that mediated. That is, it may not be an
9 allergic reaction. And our sense was that in the
10 process of the three doses, we were sort of
11 screening out those who, for whatever reason,
12 were predisposed to react. Now whether those
13 have been screened out and would not get a
14 booster dose and therefore the rate of reaction
15 on the booster dose is lower, we simply cannot
16 say. But that may, in fact, be the case.

17 The other possibility, and we have
18 absolutely no data for this, is that if there is
19 an allergic component to this, perhaps we've
20 sensitized the people and there may be an
21 increased rate of booster doses. But the bottom
22 line is there is no information about this. What
23 is the mechanisms and no information about what
24 is the reaction rate to boosters.

25 COMMANDER MAY: Yes, sir?

1 DR. POLAND: Well, if I understood
2 your data correctly, what we really have is a
3 single, small, non-randomized, non-controlled
4 observation.

5 COMMANDER MAY: I was hoping that the
6 study's author could address whether or not they
7 think there is anything unrepresentative about
8 the small sample that was taken to run the serum
9 three years later?

10 DR. POLAND: Well, how do you know?

11 COMMANDER MAY: Is there any reason to
12 think the people who weren't tested were
13 different?

14 COMMANDER DEFRAITES: Well, we'd like
15 to restore the faith of the individuals in the
16 study. Considering the fact that this was the
17 only cohort that had been identified that we had
18 pre-immunization and post-immunization serum on
19 and were able to follow up three years later, we
20 used what we had. We admit it is non-randomized,
21 but it is the only thing we have. So, I guess --

22 DR. POLAND: Certainly, I understand
23 that. And what it does is provide data to test
24 the hypothesis. From a scientific point of view,
25 I think we have inadequate information to make --

1 as much as I would like to, because it is not an
2 optimal vaccine in terms of its reactogenicity.
3 I think we have suboptimal information to make a
4 change.

5 COMMANDER MAY: You think that somehow
6 those other 247 were -- had different types of
7 antibody resistance?

8 DR. POLAND: I think as we have
9 learned over and over again in science, you don't
10 know until you do it.

11 COMMANDER MAY: Right.

12 DR. ASCHER: We have been shown on
13 several occasions the Army, Navy, Air Force serum
14 repository and the resource that represents and
15 have spoken to the issue that that should be
16 preserved. What a better opportunity to find a
17 couple hundred people that have been in this
18 situation.

19 COMMANDER DEFRAITES: We used that for
20 this study. That is where the sera came from.

21 DR. ASCHER: And you could only find
22 26?

23 COMMANDER DEFRAITES: Well, that is
24 all that were left on active duty that had an HIV
25 -- the serum repository is all routine drawing of

1 HIV serum as banked. So for most military --
2 well, the services differ a little bit with the
3 routine with the schedule. In general, every
4 other year on your birth month you get an HIV
5 test unless you are deployed and then you get it
6 more often. And of the original 286 that had not
7 received a booster -- our original study, we
8 offered a booster to everybody. Well, 286 of
9 them weren't there to volunteer to get a booster.
10 Some of them had already left the service. So
11 they didn't get a subsequent HIV test. And as
12 three years progressed, that shows you the
13 attrition in the military. So really that 39
14 were the only ones who had been in the original
15 study, had not received a booster, and were still
16 in the military and got an HIV specimen drawn and
17 in the serum bank at three years after their
18 original dose.

19 DR. ASCHER: I will modify my comment.

20 What a wonderful use of the serum repository.

21 What a wonderful use of the serum repository.

22 UNIDENTIFIED SPEAKER: Was this both
23 Army and Marines, then?

24 COMMANDER DEFRAITES: Well, this was
25 just an Army unit from Schofield Barracks.

1 COMMANDER MAY: Right. We believe
2 there is large cohort of Marines out there who
3 have had their last booster or their initial
4 series more than two years ago.

5 DR. ASCHER: Oh, okay. Well, then my
6 comment stands.

7 COMMANDER MAY: We don't think we have
8 bank serum on them.

9 DR. KULLER: Could I clarify one
10 thing? The 39 or so in the study, they were not
11 back in Okinawa or not exposed again during this
12 period?

13 COMMANDER DEFRAITES: They said not.
14 Of the 39, we were able to establish telephone
15 contact with 26 of them, and 17 of them said that
16 they had not gotten a booster since the original
17 series to their best knowledge and they had not
18 traveled in the endemic area. And those were the
19 ones that 16 out of 17 still had detectable
20 antibody over 1:10 level.

21 It wasn't a big difference. If they had said
22 they had traveled, there was no real difference
23 between the two groups.

24 DR. KULLER: What percentage of having
25 titers less than 1:10 would you accept before you

1 would recommend a booster?

2 COMMANDER DEFRAITES: What percent --
3 in other words, how high --

4 DR. KULLER: If 80 percent were above
5 1:10 and 20 percent were below, would you
6 recommend that everybody get a booster?

7 COMMANDER DEFRAITES: Well, I can tell
8 you this. The 80 percent level was not good
9 enough to get a 2-dose primary series by. We had
10 to go 3 doses and get a 95 to 99 percent sera
11 conversion rate to start with. So trying to
12 project on what the FDA might agree is acceptable
13 --

14 DR. KULLER: But right now you have 1
15 out of 16 are below 1:10. So right now it is
16 about 6 or 7 percent and the confidence limits
17 around that would get you up to probably 15
18 percent or 18 percent for just 16 people. So
19 that is why I asked. I mean what is the critical
20 level here that says we should boost everybody.

21 COMMANDER DEFRAITES: Well, I would
22 like to defer, actually, to Colonel Hoke. I
23 think he might be able -- because in terms of
24 what we might approve, if you don't have a
25 resting detectable antibody, you may get a

1 boosting phenomenon with exposures.

2 COLONEL HOKE: I think the critical
3 issue, of course, is protection. The antibody is
4 just a surrogate -- a pretty good surrogate
5 probably. But I doubt that -- I just don't think
6 that it is ever possible that you are going to
7 see prevention data out that long. But I think
8 that it is clear that 100 percent of recipients
9 of an initial series in contrast to some earlier
10 studies that I think you alluded to that showed a
11 poorer immune response in Americans with the
12 recent group with a vaccine that is licensed, out
13 of the 540 that were in Bob's study at Schofield
14 Barracks, I think all of them developed
15 substantial levels of neutralizing antibody
16 regardless of the specific schedule that was
17 used. So that is why I say virtually 100 percent
18 of people developed antibodies.

19 Now that means that they have been
20 exposed to the antigens in the vaccine and when
21 immunized again will have a antigenisstic
22 response. Or when immunized or challenged by a
23 naturally occurring infection. So I think that
24 it is a little hard to base a specific
25 recommendation on a prevalence of antibody, but I

1 would say that certainly if there were -- if it
2 were zero percent with antibody, then you would
3 need one boost. If it was 50 percent had
4 residual antibody, well you still would be
5 confident that they all had had antibody at one
6 time. But you might feel more like doing it.
7 But at 80 percent, I think you would still be
8 confident that at least the vast majority of your
9 population had been -- was sensitized.

10 DR. KULLER: I would say there were 2
11 actually. Two respondents at the bottom of Table
12 2 in the handout -- two respondents at 3 years
13 had less than 1 percent.

14 DR. BROOME: But also 2 at 6 months,
15 which was very interesting. In the text of the
16 JID article. And actually, Lou, I think your
17 question is a very good way to look at it. But
18 another thing that I am struck by is the
19 kinetics. You could also just say -- even with a
20 small number, you can see that most folks are not
21 dropping rapidly. They are leveling off fairly
22 slowly. And whether that gives you any more
23 precision in saying what you expect, instead of
24 just saying it as a dichotomous, what is the
25 lower limit of the CI that you would accept, you

1 could also look at the trend.

2 DR. KULLER: I don't think it is the -
3 - my concern is that I don't think it is the
4 population mean or median titer that is the
5 critical question here. It is really the
6 percentage of individuals who drop below a
7 certain level. Now you may say that those
8 individuals are still protected and that if they
9 were exposed they would still get a response, but
10 you don't have any evidence for that one way or
11 the other here. I mean clearly that evidence is
12 not existent.

13 DR. BROOME: Yes, but my point would
14 be that they didn't drop. I mean, at 6 months --

15 DR. KULLER: If they are the same two
16 people.

17 DR. BROOME: If they are the same two
18 people, they may not have been responders at the
19 outset.

20 DR. KULLER: We could find that out.

21 DR. BROOME: But actually, can you
22 tell me why they were getting boosters every year
23 given the package insert and the --

24 COMMANDER DEFRAITES: This study was
25 done before the vaccine was licensed and the

1 Japanese package insert translated in English
2 said give it every year. So we started out --
3 actually, could we show that other slide? Could
4 we show that slide back again? Because I think
5 you might get an idea of the kinetics. Again, it
6 doesn't answer your question about what
7 percentage, but if you look at the -- between the
8 6-month and the 1-year point before they got
9 their booster, which is between here and here,
10 this kind of gives you an idea at least where the
11 first curve is heading. Actually, this is two
12 different groups. He has got a 07 in 30-day
13 initial primary series, and then he's got a 07 in
14 21 days. But they both converge this way. And
15 if this line is projected out, it is not even as
16 good as what we found here at the 2 and 3 year.
17 This just kind of gives you an idea of whether
18 the antibodies -- they had already started --
19 they got their scheduled here, and between 6
20 months and a year, it kind of leveled off. So
21 that curve, if we dare project it out that far,
22 looks like they should have protective antibodies
23 for years.

24 DR. ASCHER: What would a 2-year
25 interval do to your logistics?

1 COMMANDER DEFRAITES: A 2-year
2 interval?

3 DR. ASCHER: Yes.

4 COMMANDER DEFRAITES: That is what we
5 have now.

6 COMMANDER MAY: A 2-year interval is
7 what we have now.

8 DR. ASCHER: I'm sorry.

9 COMMANDER MAY: It means vaccinating a
10 lot of people that may have adverse reactions but
11 not get any more protection.

12 DR. WOLFE: The Japanese have done
13 considerable work on this vaccine dating back
14 many years. I imagine the vaccine itself may
15 have changed somewhat, but there is an awful lot
16 of data in the Japanese literature. Have they
17 always used 2 doses so that it wouldn't
18 necessarily be comparable to this? Or are there
19 series where 3 doses were used at the same
20 interval and that they have done some long-term
21 serological follow-up? I mean some of these
22 papers may even be in Japanese and you might have
23 to get translations.

24 COMMANDER MAY: Exactly. I have not
25 translated any papers from the Japanese. As far

1 as I know, the Japanese have always had this 2-
2 dose series, and we have had recent unwanted
3 anecdotal experience in using the Japanese
4 vaccine in a 3-dose series and had an incredibly
5 high adverse reaction rate.

6 DR. WOLFE: Isn't the vaccine made in
7 Japan?

8 COMMANDER MAY: Yes, it is.

9 DR. WOLFE: So what are you saying you
10 are using the Japanese vaccine and getting a bad
11 reaction?

12 COMMANDER MAY: It was not
13 manufactured by the same --

14 DR. WOLFE: By Bikin?

15 COMMANDER MAY: Right. It was Takita.

16 DR. KULLER: Laurel, I think you are
17 talking about -- which reactions are you talking
18 about? The ones associated with the trial in
19 Okinawa or the three recent ones?

20 COMMANDER MAY: No, the three recent
21 ones. Yes?

22 CAPTAIN CUNNION: The original strain
23 of virus studies were done on a not-virus strain
24 that is being used in the vaccine now in Japan.
25 That was changed without doing any studies? They

1 just said it looked like it had better
2 antigenicity to it and they changed it.

3 COMMANDER DEFRAITES: Well, if someone
4 from Connaught is here, my understanding is that
5 the vaccine that is used in the United States is
6 till Nokoyama strain, which is what -- the
7 monovalent Nokoyama strain.

8 CAPTAIN CUNNION: The original strain,
9 which the Japanese are not using today.

10 COMMANDER DEFRAITES: That has gone
11 back and forth. Yes, they were using the Beijing
12 strain, but I think the vaccine that is exported
13 -- and again, somebody from Connaught could
14 answer the question better than I could. But my
15 understanding is that use in the United States
16 and elsewhere in the world, they are using the
17 Nokoyama strain. But in Japan, they are using
18 the Beijing strain for their own use.

19 DR. WOLFE: It says here, Nokoyama NIH
20 strain in the package insert that we have.

21 COMMANDER MAY: Right. That is the
22 licensed product that is labeled by Connaught and
23 manufactured by Bikin. And we think that Bikin
24 manufactures a second variety.

25 CAPTAIN CUNNION: Yes. I agree.

1 COMMANDER MAY: Okay. Yes?

2 COLONEL LEWIS: We also have to
3 consider in here too that only the company -- the
4 manufacturer, the one that holds the ELA and PLA
5 can approach FDA and they need the quality of
6 data for the name of their company and they need
7 an incentive as to why they should sell less
8 vaccine to file in FDA for a change in what the
9 label says.

10 COMMANDER MAY: Right. That is one
11 reason why we are not --

12 COLONEL LEWIS: And that is a very,
13 very big issue.

14 COMMANDER MAY: The Navy has asked me
15 to ask the Armed Forces Epi Board instead of
16 going through ACIP.

17 COLONEL LEWIS: But it is only the
18 company who holds the ELA and PLA that can
19 interact with FDA and have this printed and
20 filed.

21 DR. ASCHER: I think we can come to
22 closure to this almost in the sense that if you
23 were to ask me the other way around, what would
24 be the basis for preserving a 2 versus a 3, I
25 would like to see kinetics that would suggest

1 something is happening between 2 and 3. And this
2 is very flat kinetics. Very stabled on the data
3 you have. I would say there is basically no
4 reason why we wouldn't use a 3-year, if we accept
5 a 2-year. And I think that is the answer and we
6 would go on to the next topic.

7 COMMANDER MAY: Thank you very much.

8 DR. ASCHER: Any objections?

9 DR. POLAND: We couldn't get away with
10 this on the FDA. There is no way. This is
11 insufficient data. I mean, my guess is the data
12 is right, but it is insufficient to make that
13 judgment.

14 DR. KULLER: I would feel the same
15 way. And it seems to me that you probably would
16 have -- you know, we would call this from the
17 FDA's perspective a phase 1 or a phase 2 study,
18 and you would probably have to do a phase 3
19 study, which there is nothing wrong with that,
20 but I think basically you would have to go out
21 and get more sera and basically prove your point.

22 I think you could make the change now yourself,
23 and collect -- as is often happens -- and collect
24 more phase 3 data as long as you did monitoring.

25 That is a certain risk factor.

1 COMMANDER MAY: We would be happy to.
2 We are also interested --

3 DR. KULLER: There is a certain risk
4 involved in that because you are -- you still
5 have 2 people -- it is the number of people who
6 may not be protected. And if you are using
7 antibody titer, which may be the wrong thing, but
8 that is what you are basing it on --

9 COMMANDER MAY: It is the best
10 approximate measure of protection we've got.

11 DR. KULLER: Mean and median titers
12 really don't mean very much. The only thing that
13 means anything is going to be the percentage of
14 people who might be not protected very well at
15 the end of 3 years. And right now you have 2 out
16 of 16 that fit into that box. That is --

17 COMMANDER MAY: Or 2 out of 39.

18 DR. KULLER: Well, whatever. But
19 there are still 2 of them sitting there. And at
20 least the way the tables are written, it looks
21 like it is 2 out of 16 in this paper. So that you
22 are in a sort of an unpleasant situation.

23 COMMANDER MAY: Well, but we do think
24 we have the population to collect additional
25 sera.

1 DR. KULLER: But you only have 16
2 people.

3 COMMANDER MAY: But we would like to
4 start collecting it from people who have been
5 vaccinated with boosters greater than the 3-year
6 interval.

7 DR. KULLER: But you may have more --
8 you said there is a possibility that there may be
9 more sera available now to look at this in the
10 bank somewhere.

11 DR. ASCHER: From the Marines?

12 COMMANDER MAY: I don't know about
13 bank sera from the Marines.

14 COMMANDER DEFRAITES: The Marines and
15 the Navy aren't part of the original collections
16 from the HIV sera.

17 DR. ASCHER: Get 100 sera, and then
18 you can tell us the exact counts.

19 DR. BROOME: Two points. I mean one,
20 obviously, that is a very small number. On the
21 other hand, I think having information about
22 timing of boosters has traditionally been based
23 on much smaller numbers than original licensure
24 or some of the other kinds of questions you try
25 to answer. I do think it wouldn't be hard to

1 define the sample size you would need to exclude
2 a sero conversion rate of lower than 90 percent
3 or a sero protected level of less than 90
4 percent. I mean, you've got the problem that if
5 everybody is getting a 2-year booster, but I
6 don't know if there is any opportunity to take
7 your HIV bank specimens and follow up folks who
8 have left the service. I mean, I would think
9 there would be a way of pretty rapidly getting a
10 number you would need to exclude a less than 90
11 percent response for three years out.

12 I mean just to throw that. If you
13 asked us what further data would we like. I
14 don't think if we were looking for data --

15 COMMANDER MAY: Yes, I don't know how
16 random we can get a sample of. Certainly, I have
17 been 2.5 years. I would volunteer. But in going
18 to any group that is about to get their next
19 immunization, I don't think that it is going to
20 be random.

21 DR. BROOME: Yes. You can tell them
22 that they can not have a shot that has a 10 in
23 10,000 risk of urticaria.

24 DR. KULLER: You could split them up
25 now. I mean, you certainly could do that in the

1 sense of doing these. That would be perfectly --
2 given the data you have now, that would be
3 perfectly legitimate as long as they knew and
4 they had signed informed consent of whether they
5 did or didn't get a booster shot at this time and
6 then just basically follow them for three years.

7 Especially the ones who aren't going to Okinawa
8 and you were going to give a shot who were
9 sitting in California right now and aren't going
10 to go to Okinawa. There is no real risk to that
11 group at all, and you can basically just get them
12 to participate and just randomly assign them to
13 either a booster shot or no shot at all and then
14 follow them for one year and get a serum and then
15 in a short while you can have an answer.

16 COMMANDER MAY: If the board has
17 specific recommendations on how big that sample
18 size should be, I think we can manage it. Thank
19 you.

20 COLONEL FOGELMAN: Thank you,
21 Commander May.

22 DR. KULLER: Yes, thank you. The next
23 speaker will be Dr. Peter Jahrling from Senior
24 Research Center at USAMRIID. He will talk on an
25 update on the smallpox issue, and I think we are

1 all familiar with the board's deliberations with
2 regards to what to do with the smallpox. This
3 has hit the newspapers again hot and heavy in the
4 last month or two.

5 DR. JAHRLING: Thank you. This
6 afternoon I was scheduled actually to present
7 overviews of two DoD programs dealing with
8 viruses and biological warfare defense. Those
9 viruses were smallpox and the fila virus group,
10 Marburg and ebola. Both are seen as potential
11 concerns as both strategic and terrorist weapons.
12 But because of time constraints and the interest
13 in smallpox, I am going to limit my remarks
14 mostly to smallpox. If there is a little time at
15 the end, there is one or two slides I would like
16 to share with you regarding ebola.

17 The AFEB executive council was
18 instrumental in developing a collaborative plan
19 with the Department of Health and Human Services
20 to address potential vulnerabilities in the
21 defense posture of the nation on should the
22 remaining stocks of smallpox be destroyed. I
23 will outline that plan, report the progress, and
24 offer an opinion regarding the timetable to
25 destroy smallpox.

1 As everyone knows, naturally occurring
2 smallpox has been eradicated from the planet as
3 this WHO publication declared in 1980. The only
4 declared stocks of variola now reside in
5 Novosibirsk, Russia and at the CDC in Atlanta.
6 Retention of these stocks is seen by many as an
7 untenable risk. Ceremonial destruction of
8 variola has been scheduled and subsequently
9 delayed several times over the past several
10 years.

11 In the fall of 1994, the National
12 Security Council asked the DoD and HHS for
13 specific scientific input regarding variola
14 destruction, at that time scheduled for June of
15 1995. What ensued was a highly spirited debate
16 which ranged from the scientific to philosophical
17 to political. Following many inter-agency
18 meetings, some of which included classified
19 information regarding the threat of variola as a
20 biological warfare weapon, a joint plan was
21 presented to the National Security Council to
22 address scientific concerns which required
23 resolution before the U.S. position could be
24 resolved.

25 The joint DoD/HHS panel identified

1 three areas for research. The first was the
2 issue regarding whether the existing smallpox
3 vaccines actually do protect against variola in
4 the form and dose of a hypothetical biological
5 warfare attack. While vaccinia is credited with
6 the eradication of the virus in natural settings,
7 natural transmission of variola is thought to
8 entail low infectious doses in droplet or fomites
9 dissemination as opposed to high doses in the
10 form of fine particle aerosol.

11 A second area of concern was
12 identification of an anti-viral drug with
13 efficacy. Marbaran is a thiosemicarbozone with
14 an unknown mechanism of antiviral activity.
15 Marbaran was the only drug ever used against
16 variola. It was perceived to be only marginally
17 effective and then only prophylactically, never
18 used successfully for therapy. Moreover,
19 Marabaran is no longer available. Surely a more
20 modern antiviral drug could be found.

21 And finally, there was interest in
22 decentralizing the U.S. orthopox virus expertise.

23 A plan was developed to augment the capability
24 existing at CDC by duplicating critical elements
25 at USAMRIID and to execute a joint program to

1 improve critical deficiencies in the diagnostic
2 strategy available for orthopox viruses. While
3 this plan was being developed, the U.S. delegate
4 to the World Health Assembly was instructed to
5 call for a one-year delay in the scheduled
6 execution date for variola. It was postponed
7 until June of 1996. This plan was approved in
8 July of 1995 and funded for the remainder of
9 fiscal year 1995 soon thereafter.

10 Basically we had from July of 1995
11 until early January of 1996 to develop the
12 promised information. That deadline was set so
13 that we would have an answer before the World
14 Health Executive Council meeting which was
15 scheduled for January of 1996.

16 We did make significant progress in
17 all three areas. Regarding the vaccine question,
18 one of the arguments against testing the vaccine
19 for efficacy against variola in an aerosol form
20 is that no suitable animal model exists.
21 Commonly obtainable primates do not develop overt
22 disease and other vertebrate species are not even
23 infectable, which is probably why global
24 eradication was successful. However, Dr. Joe
25 Esposito at the CDC suggested that the question

1 might be addressed by substituting monkey pox
2 virus which does cause systemic disease
3 resembling smallpox in macaques and rhesus
4 monkeys following peripheral infection. There
5 was no data available regarding aerosol
6 infections, however.

7 The reasoning was that if a monkey pox
8 model could be developed, it was reasoned that a
9 critical question of vaccinia-induced protective
10 immunity could be addressed by testing protection
11 against aerosolized monkey pox. If protection
12 against inhaled doses of 10,000 infectious units
13 of the serologically distinct monkey pox virus
14 could be demonstrated, it would be reasonable to
15 infer protection against the serologically more
16 closely related variola virus as well.

17 On the other side, partial or complete
18 failure of vaccinia to protect against
19 aerosolized monkey pox might raise sufficient
20 concern to justify systematic development of a
21 primate model using variola. Conversely positive
22 results would preclude the need for additional
23 tests using variola. So basically if the
24 vaccinia-immunized monkeys resisted challenge
25 with aerosolized monkey pox, we would declare

1 success.

2 The first task was to select a monkey
3 pox virus strain as the appropriate surrogate.

4 The reference straining, which has been published
5 for years, was the Copenhagen strain, but
6 Esposito suspected that it had become lab
7 attenuated and suggested that we include a second
8 virus from first passage isolate from a fatal
9 human case which occurred in Zaire in 1972.

10 This choice was fortunate because the
11 Zaire strain was substantially more virulent for
12 cynomolgous monkeys than Copenhagen. Five of six
13 monkeys exposed to 30,000 plaque-forming units of
14 the aerosolized dose of this virus died 9 to 12
15 days after exposure with bronchopneumonia,
16 exanthema, enanthema, and consistent monocytosis.

17 The bottom line was that monkey pox Zaire
18 appeared to be an adequate model for human
19 smallpox. I will show you the clinical pathology
20 results in a few moments to back up that
21 assertion.

22 We thus initiated a challenge
23 experiment using monkey pox and the standard
24 commercially available Wyeth strain of vaccinia.

25 All of the vaccinated animals had successful

1 takes, as evidenced by a skin lesion, plus
2 demonstrable sera conversion by ELISA, and
3 neutralization not only to vaccinia but to the
4 challenge of monkey pox that had been immunized
5 five days previously with vaccinia. We
6 challenged them by aerosol with 10,000 plaque-
7 forming units of monkey pox Zaire. All six
8 animals remained totally asymptomatic and free of
9 infectious virus detectable by cultivation of
10 peripheral blood lymphocytes on viral cells.

11 In contrast, the six non-immunized
12 controls became extremely sick. Two died and all
13 were febrile with exanthema, enanthema, cough,
14 nasal discharges, and virus isolatable from their
15 buffy coat PBLs.

16 The conclusion was that Wyeth
17 protected against an aerosol challenge with
18 monkey pox, simulated a BW variola attack. This
19 slide summarizes clinical observations and
20 hematologies in the first control group of
21 monkeys that were exposed to 30,000 PFUs by
22 aerosol. This title should say 6 and 9 days, not
23 just 9. Five of the six monkeys died between
24 days 9 and 12. On day 7, five of the six animals
25 were febrile. Normal temperature in a cymalagous

1 monkey is 100 to 101 degrees Fahrenheit. These
2 guys had a mean of 103. On day 7, five of six
3 were febrile, 3 had an absolute and a relative
4 monocytosis. By day 9, all had skin lesions
5 denoted by the Y's, yes for exanthema and
6 enanthema listed here, and they all had coughs
7 and all but one that were destined to die had
8 nasal discharges as well.

9 We obtained similar data in the
10 critical challenge experiment. These are the
11 pre-exposure values. As I said, 100 to 101
12 degrees is normal temperature. A typical
13 differential is 5 to 6 percent monocytes. As I
14 listed in one of the previous slides. numerous
15 other parameters were measured but basically
16 these were the ones that turned out to be
17 critical. By 7 days, all 6 control monkeys had
18 developed clinical signs. These are the controls
19 here. They all had exanthema and enanthema and
20 coughs. Most were developing nasal discharges.
21 They were febrile, 102.6 on the mean, and 15
22 percent monocytes.

23 In contrast, the vaccinated controls
24 were absolutely free of detectable lesions, their
25 temperatures were 100.7 on average, and their

1 monocytes were just as they should be at 6
2 percent.

3 By 9 days after infection, all 6
4 control animals had progressed in the development
5 of lesions. They had exanthemous lesions ranging
6 from only 1 up to 38 that we counted on the body.

7 One control monkey died on day 9, and they all
8 had fevers, as you can see, coughs, and nasal
9 discharges. The virus was isolated from the
10 buffy coats of all six controls.

11 In contrast, the vaccinated animals
12 continued to remain normal. No visible lesions.

13 No fever. Monocyte counts were essentially
14 normal. And this continued through day 21. All
15 six animals remained totally asymptomatic. Viral
16 isolation attempts from all six immunized animals
17 were also negative. They did have a transient
18 elevation in their ELISA titers to vaccinia,
19 suggesting that they did recognize the monkey pox
20 aerosol challenge and responded immunologically.

21 So this is our evidence that vaccinia Wyeth did
22 confer protection against an aerosolized monkey
23 pox virus of the dose and magnitude that you
24 would expect in a BW scenario.

25 Now I would like to spend a few

1 minutes showing you a few of the histopathologic
2 and gross findings to hopefully convince you that
3 the monkey pox model is a reasonable surrogate
4 for human smallpox. This table documents that we
5 necropsied 10 lethally-infected monkeys that died
6 following aerosol exposure to monkey pox. All 10
7 were examined by conventional H&E plus
8 immunostaining for monkey pox antigen and for
9 viral isolation, and 6 of the 10 animals were
10 examined by electromicroscopy as well.

11 All 10 monkeys developed a
12 multisystemic disease. The deaths in all 10
13 monkeys were attributed to fibrinonecrotic
14 bronchopneumonia and a constellation of other
15 lesions, which I will mention, as a direct result
16 of the monkey pox infection. In one case,
17 terminal bacterial sepsis and DIC were thought to
18 have contributed to death.

19 Pulmonary lesions attributable to
20 monkey pox infection were characterized by
21 necrosis at 50 to 100 percent of bronchial and
22 bronchiolar epithelium. Airways and alveolar
23 spaces were filled with edema, fibrin, and
24 inflammatory cells. This is a gross picture of
25 lung with a darkly mottled appearance and a

1 hemorrhagic area that is visible here. Just
2 another picture from another lung showing the
3 hemorrhagic lesions that were seen in all 10 of
4 these animals. Microscopically, the architecture
5 is totally destroyed. The airways are filled
6 with edema, fibrin, and inflammatory cells. In
7 alveoli -- deep down here, these are the alveoli
8 -- this is all fibrin and inflammatory cells.
9 There is necrosis covered with hyperplasia in the
10 remaining Type II pneumocytes.

11 By immunohistochemistry, monkey pox
12 antigen is in all the affected airway epithelium
13 and in the proliferating fibroblast-like cells in
14 the interstitium, macrophages, and pneumocytes.
15 See this here at low power and at higher power in
16 a bronchiole. These are the fibroblast-like
17 cells containing replicating pox virus antigen in
18 the interstitium. Deeper down in the alveoli is
19 a similar distribution.

20 By electron microscopy, the
21 distribution of monkey pox virions as seen here
22 correlates almost exactly with the immunized
23 chemical results. In the trachea, there is a
24 similar picture. This was a consistent finding
25 in all 10 animals examined. Necrosis and

1 ulceration were offset by areas of proliferation
2 in the trachea as seen here.

3 All 10 monkeys also developed a
4 lymphadenitis with necrotizing lesions centered
5 on the lymphoid follicles. Splenitis was seen in
6 9 of 10 and tonsillitis and thymitis in most.

7 This is a low-power H&E of a
8 mediastinal lymphoid in the deep cortical areas
9 of the spleen. You see rather extensive necrosis
10 in the deep cortical areas of the lymph node. A
11 similar picture here in the white pulp of the
12 spleen. The same pattern here in tonsil and in
13 thymus.

14 In skin, the papulovesicular
15 dermatitis that we normally associate with pox
16 virus infection was also seen in all 10 animals.

17 I showed you the lesion count before. It varied
18 from only a few to widespread distribution as
19 listed there.

20 The histologic changes are also
21 listed. Surprisingly, although we looked for
22 them, we only saw inclusion bodies in the cells
23 of one animal.

24 These are pictures of animals that
25 came to necropsy. This is one of the more

1 severely infected with pox lesions on the face,
2 on the leg, in the scrotal area, and even on the
3 hands. This is a low-power H&E showing
4 epithelial hyperplasia with necrosis. And at
5 higher power, one can see infiltration of the
6 epidermis by neutrophils and at the margins of
7 the lesions ballooning to degeneration is also
8 apparent.

9 This electron microscopy of varians in
10 association with this lesion. Basically, it is
11 Koch's postulates fulfilled.

12 For the oral cavity, suffice it to say
13 that the histopathologic changes were similar to
14 those seen in the skin. Here is the tongue of
15 one of these animals. Lesions on the soft
16 palate. It is kind of hard to photograph, but
17 they are in all the animals.

18 In the GI tract, not surprisingly
19 mucosa lesions were associated with the
20 underlying gut associated lymphoid tissue. 6 of
21 the 10 animals had a severe necrotizing colitis
22 and an ulcerative gastritis was seen in 2 of 10.

23

24 This is a distant colon showing
25 lesions associated with colitis. This is the

1 gastric ulcers seen in 2 of the 10 animals.
2 There were also consistent lesions observed in
3 the reproductive tracts of both male and female
4 monkeys. This is a summary of the pathologic
5 evaluation of these animals. These monkeys
6 resembled the picture we would expect for humans
7 exposed to variola in a BW scenario.

8 We completed this experiment with
9 minutes to spare, I think, before the results
10 were due at the NSC. And although we don't
11 apologize for it, we certainly raised as many
12 questions as we answered. The results do make us
13 feel better about vaccinia efficacy than we did
14 before, but there is surely a dose at which
15 vaccinia immunity can be overwhelmed. Do we want
16 to know the answer to that question? I don't
17 know. We might also want to test the efficacy of
18 the new DoD cell culture-derived vaccinia that
19 you've heard about in previous AFEB briefings.

20 There is also the question about
21 recombinant vaccines, which use vaccinia as the
22 vector to elicit protection against other
23 antigens, elicit protective efficacy against
24 smallpox. For example, would the vaccinia hantan
25 construct now being developed to protect against

1 hantavirus disease also protect against variola.

2 We can't just use these things in a vacuum.

3 Another question is the duration of
4 immunity. These animals were challenged at 45
5 days. Surely we would like to know how long that
6 immunity can be expected to last, but that is an
7 experiment that you can't accelerate. However,
8 we feel confident for the remaining vaccine-
9 related questions, at least, that monkey pox is a
10 suitable surrogate for variola, and retention of
11 variola for that purpose would no longer be
12 required, which is what this study was all about.

13

14 Now I am going to briefly report on
15 the progress of the antiviral drug effort.
16 Clearly an antiviral is needed to treat both
17 civilian and military populations who are by and
18 large non-immune now who might be the target of a
19 BW or a terrorist attack. The strategy is to
20 test drugs that are already approved or close to
21 approval by the Food and Drug Administration for
22 an indication other than variola, for which
23 nobody is testing now. There are plenty of
24 potential targets for an antiviral drug to act in
25 this very complex virus.

1 The plan was to include variola in
2 cell culture antiviral drug screens at the CDC to
3 identify -- well, in part to identify antiviral
4 drugs, and in part to identify the appropriate
5 surrogate orthopox virus which could then be used
6 in place of variola if further work is required
7 on drugs after destruction.

8 Once identified, promising candidates
9 would be tested in appropriate animal models, and
10 by this process we would select a candidate to
11 push through for IND approval. Dr. Huggins from
12 USAMRIID went to the CDC during November and
13 evaluated 5 classes of drugs against variola and
14 5 potential surrogate orthopox viruses. This is
15 the basic design of the test. It was basically a
16 plaque reduction assay on both viral and BSC 40
17 cell culture monolayers in which the inhibitory
18 dose or ID50 is determined by serial dilution of
19 the drug versus a constant concentration of the
20 viruses that are listed there. Note that there
21 are three strains of variola, two majors and a
22 minor, as well as monkey pox, camel pox, cow pox,
23 and vaccinia. Note also that this assay
24 determines toxicity profiles for each drug, at
25 least in cell culture.

1 This table, which I realize can't
2 really be read well, although I did hand out
3 copies of it in the hard copy, summarizes the raw
4 data. The numbers are ID50s and thus lower
5 numbers are better. From this screening, 3
6 classes of drugs were identified that show some
7 promise. Some of the DNA polymerase inhibitors
8 developed for the treatment of herpes virus
9 infections had good activity against variola.

10 We are bound by non-disclosure
11 agreements with the drug companies not to discuss
12 proprietary information at an open meeting such
13 as this, but I do have some more detailed
14 information if any of the AFEB members would like
15 to see it off line.

16 Ribavirin is the drug of choice
17 against respiratory syncytial viruses as well as
18 laci fever, congo crimean, hemorrhagic fever, and
19 the hantavirus. Interestingly, ribavirin also
20 was active against variola. And what is more
21 interesting, I think, is that ribavirin had been
22 rejected as an antiviral for smallpox therapy
23 based on its high ID50, that is its low activity
24 against vaccinia. This is one of many examples
25 where surrogate viruses can lead to misleading

1 results.

2 A third class of compounds, the
3 Idenocine N1 oxide analogs were also very active.

4 And for comparison down here, you can really
5 read it, but Marbaran was tested. It had an ID50
6 of 60 as opposed to 1.4 or 0.9 for the actives.
7 So from this test, one would have concluded what
8 we already know that Marbaran is not active
9 against variola.

10 For the 3 candidates identified, it
11 was surprising that variola was more sensitive
12 than any of the potential surrogate viruses.
13 Thus, the use of surrogates would give a very
14 conservative estimate of efficacy against
15 variola. More importantly, however, no one
16 surrogate virus was identified to predict
17 efficacy of all drug classes. So it is not at
18 all clear how one would test new classes of
19 antivirals once variola was destroyed. It is
20 also not clear how the FDA will ultimately regard
21 surrogate data submitted in support of INDs for
22 treating smallpox itself.

23 Finally, a word about the diagnostic
24 effort. Lieutenant Colonel Loffs from USAMRIID
25 working with Joe Esposito at CDC has made headway

1 by importing critical elements of CDCs
2 capability, which is based on PCR of the
3 hemagglutinin gene. They have begun to PCR
4 amplify additional genetic loci. Colonel Loffis
5 is developing tests based on restriction,
6 fragment length, polymorphism, or RFLP profiles
7 for the entire genomes of representative variola
8 strains as an approach to molecular forensics,
9 which would be a concern in documenting the
10 occurrence in origin of a suspected biological
11 warfare attack.

12 This slide documents our progress to
13 date since the plan was initiated in July. Note
14 here that it was also used to track viremia or
15 actually cell associated virus in blood of the
16 monkey pox infected primates. The progress
17 report that went to the NSC in late December
18 included our conclusion that variola retention
19 was no longer required to address the vaccine
20 efficacy issues given the fidelity of the monkey
21 pox model. The best case for variola retention
22 can be made on the grounds that it is necessary
23 to bring effective antiviral drugs through the
24 approval process, especially for new classes of
25 drugs not yet identified.

1 For diagnostics, retention of variola
2 is not absolutely essential but highly desirable
3 for calibration and essential if development of
4 molecular forensics capability is desired.
5 Variola destruction has now been postponed for
6 another 3 years, until June of 1999. We hope
7 that we will be able to continue these studies
8 and to reach definitive answers by that target
9 date.

10 That is all I have to say about
11 smallpox. Do I have time to put up three slides
12 on ebola or should I stop?

13 DR. KULLER: Yes, go ahead.

14 DR. JAHRLING: Okay. Well, in the few
15 minutes I have, then, I would like to mention one
16 aspect of our work on ebola virus at USAMRIID.
17 Part of our work entails investigations of
18 natural disease outbreaks such as the one in
19 Kikwit, Zaire that captivated the news media so
20 much last summer. And now, as you probably know,
21 another outbreak is developing in Gabon. Our
22 role and that of CDC in the Gabon outbreak
23 remains to be seen as the Pasteur Institute has it
24 under control they say.

25 We sent a veterinary pathologist and

1 entomologist and a microbiologist to join the
2 field teams in Kikwit last year. They brought
3 back samples of many environmental things to
4 include rodents and arthropods in hopes of
5 identifying the reservoir for ebola in nature.
6 Presently, the 35,000 arthropods are being sorted
7 with the help of the entomologists here at WRAIR
8 and are being processed for ebola by PCR and
9 conventional isolation techniques. That work is
10 only beginning, but so far nothing has come up
11 positive.

12 CDC's tests of the vertebrates is likewise all
13 negative at this point although they are finding
14 some terrific rhinoviruses.

15 During the Kikwit outbreak, the option
16 for plasma therapy was considered but rejected by
17 most as being too marginally effective if not
18 outright dangerous. Human plasma rarely has
19 sufficient neutralizing antibody to be
20 protective. We needed a more potent neutralizing
21 antibody. Well, the Russians came along and
22 claimed that they had an effective immunoglobulin
23 preparation. The Biopreperot Lab at Novosibirsk
24 offered for a price several hundred doses of a
25 purified IGG prepared by conethenol precipitation

1 of horse serum that they had hyperimmunized from
2 animals they hyperimmunized with formalin-
3 inactivated whole virus and boosted with, if you
4 can believe it, live virus. They promoted this
5 product for use in Kikwit, but the World Health
6 Organization requested us to test its efficacy by
7 some method first.

8 USAMRIID received this material in
9 August and we tested it. It had an incredibly
10 high log neutralizing antibody titer of 4.5 logs
11 against ebola Zaire, and it is apparently very
12 pure and potent monomeric IGG -- good stuff. We
13 then attempted to repeat the published Russian
14 experiment in which they claimed to have
15 successfully treated baboons when given the IGG
16 immediately after virus challenge at a pretty
17 high dose, 6 ml of IGG intramuscularly. This, by
18 the way, is the same volume that they recommended
19 for use in humans. It turns out, if you read the
20 paper, that N=3 and one of the baboons died, as
21 did all the baboons treated 6 hours after virus.

22 Nevertheless, we tested it in guinea pigs and
23 were surprised to get positive results.

24 So we went immediately to cynamalogous
25 monkeys. These animals received 6 ml IM of the

1 IGG immediately after ebola Zaire 95 inoculation.

2 And on day 5 after inoculation, the results were
3 absolutely black and white. This is the viremia
4 going up to about 7 logs of virus in the control
5 animals that were untreated. In contrast, on day
6 5 the animals that had received the IGG were
7 totally devoid of virus and were apparently
8 normal by all of the usual criteria. However, as
9 you can see, it all changed by day 7. Basically
10 these animals spiked a viremia and died just as
11 dead as the untreated controls.

12 On the bottom panel, I have plotted
13 total IGG. You see that the total equine IGG
14 titers were passively acquired and were
15 maintained through day 8 or 9 of the experiment.

16 But what is significant, we thought, was that
17 the specific IGG titers against ebola disappeared
18 at about the same time as the viremia increased.

19 This suggested -- this gave us the impression,
20 at least, that the virus was combining with a
21 specific antibody, which then when it reached a
22 critically low point viremia would start to
23 evolve. Now we were disappointed by these
24 results, but we reasoned that there was clearly a
25 beneficial effect and that a second infusion of

1 IGG out here around day 5, when their antibody
2 titers were starting to wane, might be sufficient
3 to suppress viremias a little longer and permit
4 the host immune system to take over and activate.

5 There was a concern, though, that a
6 second infusion might cause serum sickness, so we
7 looked first at the pharmacokinetics of the IGG
8 in uninfected monkeys inoculated with 6 ml IM.
9 And here you see that following the first
10 infusion in yellow, titers were maintained at
11 more than 80 percent of their original titer for
12 about 8 days and then clearance was more rapid
13 suggesting immune clearance. This concerned us
14 because it seemed reasonable to predict the
15 second infusion might be immunologically cleared
16 or worse it could precipitate serum sickness. So
17 to test that possibility, we reinfused these same
18 monkeys about two months later. You have to take
19 my word for it that the initial titers were the
20 same in these animals that received their second
21 shot although the axis has been normalized. It
22 does appear that clearance is accelerated after
23 the second shot, although modest levels are
24 maintained for the first 4 days. And more
25 importantly, there was no evidence of serum

1 sickness.

2 So we felt it was reasonable to go
3 back and test that hypothesis that a second
4 infusion on day 5 might be beneficial. And we
5 also tested the hypothesis that pre-treatment two
6 days before challenge might restrict initial
7 viral replication sufficiently to prevent seeding
8 of target tissues and disease. The top panel
9 shows the viremia for the control versus the two
10 groups. These are the control viremias here, the
11 animals dying. This is the pretreatment group.
12 Viremias are essentially negative after 5 or 6
13 days, but then they shoot up. And the animals
14 that received a second shot on day 5, you see we
15 successfully suppressed their detectable viremia
16 all the way out here to 8 or 9 days, but
17 eventually they also became viremic. The
18 pretreated animals, N is only 3 here, but all
19 three pretreated animals died. One of the
20 animals that received two shots on day 0 and 5
21 survived, which is our sole survivor in all the
22 many tens of animals that we have infected with
23 ebola Zaire. And the specific and passive
24 antibody titers essentially mirror the viremia
25 curves as we saw before.

1 Our conclusion from all this is that
2 passive IGG may play a role in the treatment of
3 ebola Zaire, but it is unlikely to be effective
4 alone in treating human patients, especially
5 since patients are to be treated with one tenth
6 the experimental dose that we tested here on a
7 volume per weight basis. You also have to
8 consider that we optimized the conditions for
9 treatment success here and treatment efficacy
10 would certainly be less optimal in patients who
11 were viremic at the time when they come to the
12 hospital.

13 We do feel, though, that there might
14 be a role for humanized monoclonal antibodies in
15 treatment. We now have that surviving primate,
16 whose neut antibody titer is increasing every
17 day. He is going to serve as a source of bone
18 marrow cells for phage display and other
19 strategies to produce antibodies with the right
20 mix of neutralizing antibody activity and
21 hopefully more favorable pharmacokinetics.

22 DR. ASCHER: Just like in the movie,
23 right Peter?

24 DR. JAHRLING: Right. That one monkey
25 got expanded upward. Questions?

1 COLONEL FOGELMAN: Questions or
2 comments?

3 COLONEL TAKAFUJI: I have a question.
4 This is Colonel Takafuji. Dr. Jahrling,
5 realizing that the date has now been postponed
6 for the destruction of variola, what does that
7 mean in terms of the research at USAMRIID and how
8 you are being funded right now? What are your
9 priorities? Primarily antiviral work?

10 DR. JAHRLING: Right. We made the
11 case that we don't need to have variola for
12 vaccine efficacy studies although to answer your
13 question, we will go back and check the DoD cell
14 culture vaccine using advance development money.
15 So that will take place.

16 The plans to continue the antiviral
17 drug effort, which everybody involved in the
18 interagency working groups agrees is a high
19 priority of importance to both the military and
20 civilian sectors, we have not yet identified --
21 or for us, the funding sources for the
22 continuation of that project have not yet been
23 identified. And, in fact, we are continuing to
24 operate this program with fiscal year 1995 money
25 left over. We don't even have 1996 money at this

1 point. So the future of this program is
2 dependent on the continued funding. We are
3 working with Dr. Prosif trying to get that money
4 identified and sent down through the RAD-4 shop,
5 but that check is not even in the mail yet.

6 DR. KULLER: Questions? Yes.

7 DR. FLETCHER: Do you think there are
8 other sources around the world, other than the
9 CDC and Russia, that may have this virus?

10 DR. JAHRLING: This is an open
11 meeting, but I think that assumption is
12 reasonable.

13 DR. ASCHER: One of the items we went
14 out on a limb on in making these sort of
15 recommendations was that you guys were going to
16 be able to do this work in short order, and you
17 are really to be congratulated for the
18 turnaround. It restores faith in the system that
19 can do something this quickly in the face of all
20 the other competing priorities, particularly at
21 CDC. So, well done.

22 DR. KULLER: Any other questions?
23 Thank you very much. Very good. Colonel
24 Bancroft?

25 COLONEL BANCROFT: I'm just going to

1 give you a brief update on some of the recent
2 activities related to the National Vaccine
3 Advisory committee. This is an advisory
4 committee made up of non-federal members advising
5 the Department of Health and Human Services, and
6 I happen to be the DoD liaison to that group.

7 Over the years, I have presented to
8 this group that the NVAC has sponsored and
9 developed a national vaccine plan, and
10 subsequently they have also made statements about
11 childhood and adult immunization. But I want to
12 bring your attention right now to another effort
13 that is going on at the present time and that is
14 to develop a national plan for pandemic influenza
15 preparedness.

16 This has been effort which has been
17 going on in the background in a small interagency
18 group involving CDC, NIH representatives, FDA,
19 and the DoD, but now is beginning to get a little
20 more attention.

21 There have been previous national
22 plans for influenza. Since 1976, I am told there
23 have been two previous plans, but both of those
24 were considered to be insufficient because
25 although everybody was saying that we need to be

1 concerned about influenza and plan on how we are
2 going to deal with the next pandemic, there were
3 no action steps involved in this and there was no
4 designation of responsibility. In the current
5 effort, we hope to be able to correct those
6 deficiencies.

7 This is a work in progress, but it is
8 an effort to have a coordinated plan involving
9 the concerned federal agencies. But it is not
10 just federal. It also involves the states, the
11 local areas, and industry in this. It concerns
12 decision making at different points in the
13 planning of dealing with influenza. It concerns
14 how vaccine will be procured in short order and
15 how it would be distributed. It concerns the use
16 of antivirals, particularly for group Type A
17 influenza. And it also has to do with health
18 care delivery.

19 There is an area of research. This is
20 not an area that the DoD is currently involved
21 in. We are not doing research on influenza at
22 the present time, I think somewhat to the
23 chagrin of some of the people who have been
24 involved in influenza in the past. But it also
25 involves evaluation of what happens at the end of

1 a pandemic.

2 As far as I am concerned, from our
3 standpoint influenza should be considered under
4 the umbrella of global surveillance for emerging
5 and re-emerging diseases and how we are going to
6 respond to them. Everyone views influenza as the
7 emerging disease, which will happen again in the
8 future. So it is predictable in that sense.
9 What we can't predict is when.

10 The group views three important
11 periods in the transition of influenza. There is
12 the inter-pandemic period, which can be 10 to 15
13 years or much longer, and this is the period that
14 we are in now. This is the period in which there
15 are small antigenic shifts from year to year,
16 drifts if you will, and we have to adjust the
17 vaccine each year to accommodate the changes.
18 But most of the population has some level of
19 immunity to influenza and so we see increases in
20 disease rates seasonally with increases in
21 mortality seasonally, but most of the population
22 is not affected.

23 During a pandemic alert, though, this
24 is a period when it has been recognized that
25 there is a new strain of flu out there that has

1 substantial change in its antigenicity. So there
2 is a very low level of protection or immunity in
3 the general population, and most importantly,
4 transmission from humans to humans has been
5 demonstrated to occur. That, in itself,
6 distinguishes this period from what was going on
7 with swine flu in 1976. This requires sustained
8 human transmission.

9 And then there is the pandemic period.

10 The pandemic alert period could be very short.
11 And if the first strain is identified in the
12 United States, it might be very, very short
13 although we would expect it might occur outside
14 the United States. Then the pandemic influenza
15 period would be a matter of months and it might
16 have a second wave in the following season. And
17 then following that, we would go back into an
18 inter-pandemic period.

19 It is felt that one of the problems
20 during the 1976 epidemic was that during this
21 period, because human to human transmission was
22 not being followed, that there should have been a
23 point for go or no go decisions. The components
24 of this plan will involve input from the
25 Department of Health and Human Services, CDC,

1 NIH. It includes DoD, and we are going to have
2 tri-service involvement in preparing the DoD
3 section. The FDA has a role in this. Industry
4 has a role in this. And as I say, there has been
5 an interagency working group working on the
6 drafting of this for some time. But more
7 important to us, there is now a DoD inter-service
8 working group with representation from CHPPM,
9 from the Navy Environmental Health Center, and
10 from Armstrong Laboratory for the Air Force, and
11 here, WRAIR.

12 This is a work in progress. We hope
13 to have a plan which can be presented to the
14 board sometime in the future.

15 DR. ASCHER: How far in the future?

16 COLONEL BANCROFT: Pardon?

17 DR. ASCHER: How far in the future?

18 COLONEL BANCROFT: Well, I hope within
19 months. Pretty soon. Are there any questions
20 about this? Thank you.

21 COLONEL FOGELMAN: Thank you.

22 DR. KULLER: Okay. We are going to
23 break now for about 15 minutes or so, and then we
24 will have the preventive medicine officers
25 report.

1 (Whereupon, at 2:52 p.m. off the
2 record until 3:13 p.m.)

3 COLONEL FOGELMAN: Before we start, I
4 would like to introduce a new member to our
5 preventive medicine staff. Commander Trueman
6 Sharp, who is going to be -- he is a Naval
7 officer assigned to the U.S. Marine Corps
8 quarters, who is going to be giving the Marine
9 side of the picture for us in the future. First
10 we have Captain Trump from the Navy.

11 CAPTAIN TRUMP: Good afternoon, Dr.
12 Kuller and board members. I am going to go over
13 one traditional infectious disease problem
14 initially. Briefly, we did want to report the
15 initial information about a respiratory disease
16 outbreak that has occurred on the West Coast.

17 On a West Coast based cruiser that has
18 a crew of about 580, in early February they
19 reported over 50 cases of an acute febrile
20 respiratory illness. They called in for
21 infectious disease epidemiology support because
22 they were getting ready to go underway in the
23 following few days and needed to find out whether
24 they had to delay their departure because of what
25 appeared to be an outbreak.

1 An initial investigation was done and
2 it was felt to be that there was a febrile
3 illness affecting at least 50 people. Some
4 initial cultures were taken and also sera. The
5 results from those cultures have shown to date 30
6 of the 50 cultures are positive for influenza
7 virus Type A, which the laboratory is reporting
8 as being of an H3N2 presentation. Interestingly,
9 99 percent of the crew, all but 5, had reported
10 to have received the influenza vaccine during the
11 first week of December.

12 The investigation is ongoing. One of
13 the investigators is on the ship this week
14 collecting some convalescent sera and some
15 additional questionnaire information now that the
16 ship is back in port. Samples have been sent off
17 to CDC for subtyping of the virus to see how it
18 matches up with the strains that are in the
19 current vaccine. To date, there are no other
20 influenza-like outbreaks being reported among
21 Navy and Marine Corps operations, at least any
22 outbreaks of the scale that we have reported
23 here. Again, this was just an initial heads-up
24 about what is going on. We may have more
25 information at the next board meeting. Yes, sir?

1 DR. ASCHER: We heard about this as
2 well, and I was just curious if these were young
3 people who got one shot and this was their first
4 ever shot, was this something that would surprise
5 you?

6 CAPTAIN TRUMP: I am not sure what the
7 demographics are. We don't have that information
8 about who got -- you know, what percent got the
9 vaccine. Most of our recruits -- most of the
10 recruits get a vaccine when they enter recruit
11 camp if it is still available. They continue
12 giving it as long as they have vaccine available.

13 DR. ASCHER: Somebody can correct me,
14 but I didn't think you would get much efficacy in
15 this population without natural exposure and
16 previous disease.

17 CAPTAIN TRUMP: Again, we don't have
18 that information about their previous
19 vaccination.

20 DR. ASCHER: Am I wrong?

21 DR. GWALTNEY: No, I think that looks
22 like about what influenza -- the current
23 influenza vaccines will do and won't do.

24 DR. ASCHER: In young people.

25 DR. GWALTNEY: In young people.

1 CAPTAIN TRUMP: Yes.

2 DR. GWALTNEY: It gave about the
3 protection rate that is the best it can do.

4 CAPTAIN TRUMP: 80 percent, I think,
5 is what we have seen.

6 DR. GWALTNEY: Yes. That is kind of a
7 classic of what you might expect.

8 CAPTAIN TRUMP: We normally don't see
9 -- if that is the case year to year -- this is a
10 relatively unusual occurrence.

11 DR. ASCHER: It is also a cohort. You
12 are contained. You have all those other issues.

13

14 CAPTAIN TRUMP: Right.

15 DR. PEROTTA: When you say West Coast
16 based, this was West Coast and it had not been in
17 other ports of call?

18 CAPTAIN TRUMP: Not recently. They
19 were in San Diego and they went to sea and
20 currently are up in Bremerton up in the
21 Northwest.

22 DR. GWALTNEY: Did they suspect
23 influenza when it first started?

24 CAPTAIN TRUMP: The initial
25 impressions were no because the illness was not

1 as severe as they might have expected from the
2 classic influence, which again goes on with your
3 hypothesis.

4 DR. GWALTNEY: And I wondered if they
5 used amantadine to treat the cases that they did
6 have?

7 CAPTAIN TRUMP: I don't think they
8 made that recommendation. Yes, Captain Thomas?

9 CAPTAIN THOMAS: I just wanted to make
10 a note. One of the things that was interesting
11 in this initial report was that the reason why it
12 initially attracted attention was that the ship
13 was not able to get underway. The commanding
14 officer, the executive officer, the navigator,
15 and the medical officer were among the ill.
16 These were not all very young people. There were
17 some key players that were affected by this.

18 DR. GWALTNEY: That is a very nice
19 work up. Just a classic work up.

20 CAPTAIN TRUMP: They are doing a very
21 thorough investigation and there should be more
22 to present at some time in the future.

23 DR. GWALTNEY: But I do think that
24 they -- in February in influenza season, I don't
25 know what was happening there in that part of the

1 country, but certainly amantadine would be
2 useful. I am not sure they could have gotten
3 underway, but if you get it in the first 24 to 48
4 hours, it modifies the illness quite a bit.

5 CAPTAIN TRUMP: Anything else?

6 COLONEL HOKE: Just one comment
7 getting back to Colonel Bancroft's presentation
8 on the pandemic influenza plan. I mean there are
9 some things that I missed because I came at the
10 last minute, but this points out that it is right
11 that this is not a disease that we've heard the
12 last of. And on the amantadine issue, one of the
13 things that is currently in the plan that is
14 being drafted is to ask the board to address
15 rimantadine/amantadine issue as a more or less
16 strategic sort of issue. Should there be a
17 stockpile? This isn't the time to discuss it,
18 but this sort of is a harbinger of that question.

19

20 DR. ASCHER: The reason I raised the
21 issue is that there is at least one manufacturer
22 that is pushing an improved influenza vaccine for
23 this very problem, better adjuvants for example.
24 And it may end up as an orphan in general use,
25 but the question would be is this something that

1 the military should think about because this is a
2 problem the military would face. Again, young
3 people and not a lot of experience with flu and
4 limited efficacy of vaccine, crowding, and what
5 you've indicated. So at some point maybe we
6 might want to hear about this developmental
7 stuff. It is an interesting project.

8 CAPTAIN TRUMP: Colonel Bancroft?

9 COLONEL BANCROFT: Do you want to
10 point out who isolated the virus?

11 CAPTAIN TRUMP: Actually I don't have
12 -- I am not sure who.

13 COLONEL BANCROFT: Well, I think it
14 was out in San Diego.

15 DR. ASCHER: San Diego Public Health.
16 I think it was Patty Weber, wasn't it?

17 CAPTAIN TRUMP: Okay. I mean the
18 investigators are Commander Earhardt and the
19 medical center staff there at San Diego, Greg
20 Gray at Naval Health Research Center, and Dr.
21 Ledbetter and Beadle at preventive medicine.

22 CAPTAIN THOMAS: Dave, how many of the
23 investigators became ill, too, when they went
24 aboard ship? A number of them.

25 CAPTAIN TRUMP: I know some of the

1 corpsmen did. Again, I don't have the details.
2 The guy who probably has most of those is one the
3 ship continuing the investigation at this time.

4 What I would like to do is hopefully
5 relatively quickly go through some information
6 that has just come out. The DoD survey of
7 health-related behaviors among military personnel
8 was just released within the last few weeks
9 within the Department of Defense. This is one of
10 a series of ongoing surveys. It started out as
11 primarily a drug and alcohol survey in 1980. It
12 has been done every 2 to 4 years since that time.

13 The previous one was done in 1992. They have
14 been done by Research Triangle Institute under
15 contract to the services and most recently under
16 contract to the Department of Health Affairs.

17 This 1995 study, they had several
18 objectives. One was to continue looking at the
19 drug and alcohol prevalence, but the other was to
20 try to get at some of the markers or some of the
21 metrics for Health People 2000 within the
22 Department of Defense.

23 I will present some of those numbers
24 for the Navy and Marine Corps as just a taste of
25 what is available in this report. It may be of

1 interest in hearing in more detail at some later
2 presentation.

3 This was done as a 2-state cluster
4 sample of all active duty military population
5 worldwide, all four services. They excluded
6 recruits, academy students, and those who were
7 absent without leave, and also those who were in
8 a midst of a permanent stage of station moving
9 from one location to another. It was done as an
10 anonymous self-administered questionnaire. It
11 took on average about 50 minutes to complete.
12 They had over 16,000 respondents, which were 70
13 percent of those who were identified as being
14 eligible for the survey. For the Navy, a little
15 over 4,000, and for the Marine Corps just a
16 little under 4,000 participants were in the
17 survey.

18 Just some demographics of the eligible
19 respondents after they weighted and post-
20 stratified the estimates. Predominantly male,
21 almost 90 percent in the Navy and 95 percent in
22 the Marine Corps, 68 percent white in both of the
23 services, and some minor differences between
24 black and Hispanic and others. 46 percent of the
25 Navy and 58 percent of the Marine Corps

1 population had a high school education or less.
2 You can see for age, the Marine Corps in
3 particular has a much younger population. 61
4 percent were married in the Navy and 49 percent
5 married among the Marines. Predominantly 87 and
6 89 percent were enlisted members.

7 The Department of Defense has adopted
8 several of the Health People 2000 objectives for
9 the Department of Defense. Again, this is just a
10 status report based on 1995 for the Navy and
11 Marine Corps. Just to give you an idea of where
12 we stand. One of the objectives was to reduce
13 cigarette smoking to a prevalence of less than 20
14 percent among military personnel. We are
15 currently at 35 percent in both of the services,
16 Navy and Marine Corps. Those rates are above the
17 national civilian average. Fortunately, the
18 trend continues to be down, but again higher than
19 we would like.

20 Another objective was to reduce
21 smokeless tobacco use by males under 24 to less
22 than 4 percent. 21 percent in the Navy and 31
23 percent in the Marine Corps. That continues to
24 be a -- or is a significant and growing problem.

25

1 COLONEL CIRONE: Can I ask a question?

2 CAPTAIN TRUMP: Yes.

3 COLONEL CIRONE: Do you know -- this
4 is Colonel Cirone at Health Affairs. Do you know
5 what the baseline studies -- are they listed in
6 there? How well you are doing from some previous
7 point in time?

8 CAPTAIN TRUMP: There is. And this
9 survey is I think about 120 questions with
10 subquestions for the total population with about
11 40 additional questions for women's health
12 issues. The report is about an inch and a
13 quarter thick and doesn't analyze all the data
14 that is available. There is a great deal of
15 information there. The trends in some areas show
16 we are getting better in areas like smoking, but
17 there are concerns that a lot of those
18 improvements may be because the demographics of
19 our population have changed and not because we
20 really are getting at the root problems.

21 The previous studies looked at some of
22 these like cigarette smoking and a lot of the
23 others. This is the baseline data for ongoing
24 comparison in the military population.

25 One of the objectives was to reduce

1 overweight as measured by body mass index to a
2 prevalence of less than 20 percent among those
3 who were over 20 years old and less than 15
4 percent among people who are less than 20. The
5 Marine Corps is doing pretty well. The Navy, at
6 least for those over 26, is 23 percent. One of
7 the things to note, though, is the body mass
8 index that is used here is actually higher than
9 that that we set for our standards for physical
10 fitness and being retained in the service over
11 time.

12 For those that are less than 20 years
13 of age, there is some concern that the cut point
14 they used of 15 percent and the body mass indexes
15 may not be a good marker for this population.
16 Also the body mass index is pretty stringent. It
17 is below what the Navy, at least, adopts as an
18 acceptable upper limit of weight. And then also
19 that in a young physically active population,
20 does it take into account what they may be
21 carrying as weight due to muscle mass rather than
22 to fat.

23 This one hopefully should not be a
24 surprise in a military population. The DoD
25 Healthy People 2000 is greater than 20 percent of

1 the proportion who engage in vigorous physical
2 activity at least 3 times per week for at least
3 20 minutes. The Marine Corps, as expected, is up
4 there at 80 percent. The Navy is doing all right
5 at 58 percent.

6 Increasing to greater than 75 percent
7 the proportion who have had blood cholesterol
8 checked within the preceding 5 years. That goes
9 back to some of the information from Dr.
10 Fletcher's presentation earlier. For the Navy,
11 it was 54 percent. For the Marine Corps, it was
12 38 percent. Again, realizing that this is a
13 relatively young population, especially on the
14 Marine Corps side.

15 DR. FLETCHER: You have greater than 3
16 times in the physical activity. Would you
17 speculate that is 5 or 6 times a week?

18 CAPTAIN TRUMP: They collect -- that
19 data is collected. Again, what I am reporting
20 here is just how these break out with the Health
21 People 2000 objective. Again, there is a lot of
22 data in this study.

23 For blood pressure screening, there
24 were some questions about increasing to greater
25 than 90 percent the proportion who had their

1 blood pressure measured within the preceding 2
2 years. About 70 percent for both of the
3 services. And for those who are taking actions
4 to control it, 54 percent and 33 percent.

5 There were a variety of questions in
6 here that asked not only about risk factors and
7 what the behaviors were but also about what their
8 utilization of medical care was as far as visits
9 to physicians, hospital stays, days in the
10 hospital. Again, this is self-reported on the
11 questionnaire, but it does give some information
12 that isn't available through other sources to us
13 right now. One of the objectives was reducing
14 non-fatal, unintentional injuries requiring
15 hospitalization to less than 754. And again, I
16 think it was alluded to earlier. We have a
17 military population, physically active Marines
18 out there, marching, running, getting off and on
19 equipment. The injury rates are higher than you
20 would expect, at least looking at the civilian
21 norm.

22 As far as increasing use of occupant
23 protection systems, primarily seat belts and
24 others, actually doing quite well with the Navy
25 and the Marine Corps, due in part I think to

1 policies such as requiring people to put their
2 seat belts on when they are on a military
3 installation and being checked at the gate and
4 stopped if that is not done.

5 However, in the area of increasing use
6 of helmets for motorcyclists over 80 percent and
7 bicyclists to greater than 50 percent, there is
8 room for improvement for both the Navy and the
9 Marine Corps.

10 One of the goals was to increase to
11 greater than 50 percent the portion of sexually
12 active unmarried people who had used a condom
13 during their last sexual intercourse. At 43
14 percent at both services. This is somewhat
15 bothersome because in the 1992 survey the rate
16 was 50 percent. There is a decrease from that
17 previous number.

18 There was also -- one of the
19 objectives was to increase to over 95 percent the
20 portion of women who have received a pap test
21 ever or 85 percent within the past 3 years, and
22 for women in both of the services who
23 participated, those were being achieved.

24 Again, for pregnant women, increasing
25 abstinence from tobacco to greater than 90

1 percent, currently at 82 and 84 percent. The
2 second one there is increasing abstinence from
3 alcohol use in pregnant women by a delta of 20
4 percent. So this is the baseline for looking at
5 how that may be changing over time.

6 There are other results that aren't
7 necessarily in the Healthy People 2000
8 objectives, and I just wanted to present 2 --
9 just some of the data that is available. One
10 gets at some of the issues about high risk
11 behavior that people participate in indicates
12 heavy drinkers. That is defined as 5 drinks for
13 a typical session at least once a week during the
14 30 days prior to this survey. It was 19 percent
15 in the Navy and 28 percent in the Marine Corps.

16 The second bullet is a -- there were
17 several questions that got at depression and
18 about issues about stress. One that was
19 categorized as individuals who needed further
20 assessment for depression, and that was 20
21 percent for both the Navy and the Marine Corps.
22 That was defined as an extended period of
23 depression based on either a report of feeling
24 sad, blue, or depressed for greater than two
25 weeks in the past 12 months, or greater than two

1 years of life's time feeling depressed, and
2 feeling depressed much of the time in the past 12
3 months. And then in addition to that criteria,
4 feeling depressed for one or more days during the
5 past week.

6 Again, this is just an introduction to
7 let you know that those numbers are now out
8 there. This is one of three studies that will
9 come out here within the next several months.
10 The other one is the DoD survey of beneficiaries
11 in which over 160,000 mail-out questionnaires
12 were sent out to active duty members, family
13 members, retirees and their family members trying
14 to assess not only use of preventive services,
15 health status, and also utilization of
16 healthcare. The other one that Colonel Parkinson
17 may mention is the CEPRS study of clinical
18 preventive services and a record review.

19 I think all three of these studies
20 together are helping us right now try to shape
21 what the health of the military population and
22 our other populations that we support are in the
23 Department of Defense, and I think might be
24 worthy of your time on a more detailed brief at
25 some time in the future.

1 These also form part of our
2 performance indicators for Navy medicine, the
3 Healthy People 2000, and others. An additional
4 performance indicator is the rates of HIV
5 seroconversion that are being reported on an
6 annual basis. Our numbers for 1995 are complete.

7 Just to show in 1995 in the Navy, there were 85
8 seroconverters. The rate is .26 per 1000. There
9 has been a steady downward trend over the last
10 several years. The force testing is around upper
11 70's to low 80 percent rather consistently. And
12 very similar numbers for the Marine Corps -- or
13 actually better numbers for the Marine Corps as
14 far as the number of seroconverters, and then
15 their rate has consistently been lower than that
16 that is observed in the Navy.

17 Any questions about either set of
18 data? Yes?

19 DR. LUEPKER: Yes, just one question
20 about this recent survey. I assume from this
21 that it means that the participation rate was 70
22 percent? That is what you got back?

23 CAPTAIN TRUMP: Yes. And it wasn't --
24 it was the Research Triangle Institute, Dr. Bray
25 and others.

1 DR. LUEPKER: I would wonder about --
2 because there is a fair literature that suggest
3 that people like smokers don't respond to surveys
4 at the same rate as non-smokers do. Do you have
5 some sense of what the non-response population
6 looks like? I mean, you are talking about using
7 these as baseline data. And some of these
8 questions, the people that know what the socially
9 unacceptable answer is may not -- they may be the
10 people that don't send them back.

11 CAPTAIN TRUMP: This is -- as I said,
12 I didn't have a big block of time to go into the
13 details. But what they did was just a sample.
14 They identified geographic areas within those and
15 then over almost 800 of those worldwide. They
16 did a sample of those and then at those sites
17 identified individuals and had them come in to a
18 central location and the survey was administered
19 on site at that point. So it is more a matter of
20 30 percent either could not be located or could
21 not come in to the survey site. It was not a
22 mail-out questionnaire.

23 DR. LUEPKER: So the 30 percent are
24 people who didn't basically refuse to come in.
25 They were people that --

1 CAPTAIN TRUMP: Couldn't be found. It
2 wasn't that they had an option to look at the
3 questionnaire and not answer it.

4 DR. LUEPKER: That is helpful.

5 CAPTAIN TRUMP: Not necessarily send
6 it back. It is -- one of the advantages of this
7 one is that at that point they strip the
8 identifiers in it as much as possible. It is an
9 anonymous survey. They ask questions about
10 illicit drug use trying to get at high risk
11 behavior that we may not be able to capture in
12 other ways because of concerns about linking in
13 some way to an identifier. Yes, sir?

14 COMMANDER ARDAY: The percentage of
15 the force tested, is that like for a period?
16 Like within the past year, or is that simply
17 looking across the entire force at a given point
18 of time? You know 86 percent have at least some
19 tests done?

20 CAPTAIN TRUMP: No, it was for the
21 year. The number of tests collected -- the
22 number of individuals tested represents 86
23 percent of the force for the year.

24 COLONEL FOGELMAN: Have you seen any
25 change in demographics of those that are found to

1 be positive for HIV in 1995 versus previous
2 years?

3 CAPTAIN TRUMP: I don't have that
4 information. Anything else? Thank you very
5 much.

6 DR. KULLER: Commander Sharp?

7 COM. SHARP: Good afternoon. Because
8 this is the first time, at least in anybody I
9 know's recent memory, that the Marine Corps has
10 had an opportunity to brief, I want to first say
11 a few things about who the Marine Corps is and
12 what their relationship is with the Navy and the
13 Navy Medical Department. Because this is an area
14 that is often confusing to people. And I then
15 wanted to say a few words about what I have
16 termed the re-emergence of preventive medicine in
17 the Marine Corps, and then give you an idea of
18 some of the things that the preventive medicine
19 officers are working on currently in the Marine
20 Corps.

21 As many of you probably know already,
22 the Marine Corps is a service. However, it is
23 not a department. What I mean by that is that
24 the Marine Corps is one of the two services
25 within the Department of the Navy. And if you

1 look up marine in the dictionary, you would see
2 it would say something to the effect that these
3 are the troops needed to protect naval
4 installations or to help sailors on ships and so
5 forth. So the Navy and the Marines kind of have
6 this sibling relationship, both love and hate at
7 some points depending on the circumstances.

8 Anyway, one of the points I want to
9 make is that all medical personnel who deal with
10 the Marines or who are assigned to the Marines
11 are, in fact, Navy. I am, in fact, a Navy
12 officer. When you are with the Marine Corps, you
13 can opt to wear the Marine Corps uniform. That
14 is a point that often confuses people and that is
15 why I mention it.

16 The Marine Corps, even though -- I
17 mean, the relationship with the Navy medical
18 department can be a little confusing, but in a
19 nutshell the Marine Corps has medical personnel
20 who are assigned full-time to the Marine Corps,
21 such as myself. These could be called organic
22 medical assets. The Marine Corps, though, relies
23 heavily on support from the Navy. The Marine
24 Corps medical is really focused primarily on
25 supporting deployed Marines, and thus the organic

1 medical assets with the Marine Corps are what is
2 called first and second echelon. So kind of
3 front lines medical support. But in the deployed
4 environment, Marines then have to send people to
5 Navy facilities.

6 In garrison, the Marines rely almost
7 entirely on Naval personnel to meet their medical
8 needs. Now this is true of preventive medicine
9 now as well. There are some of us in preventive
10 medicine who are assigned to the Marine Corps,
11 but we rely heavily on preventive medicine in the
12 Navy.

13 Some of the fundamental traits of the
14 Marine Corps that I think can affect what we do
15 in preventive medicine are shown on this
16 overhead. The Marine Corps is, by far, the
17 smallest of the services, about 160,000 to
18 170,000 active duty. I am still trying to figure
19 out what it is that makes a Marine a Marine, but
20 something does. It is a very unique and distinct
21 culture, and this can be important in trying to
22 practice preventive medicine because I think that
23 the Marines in general view the world in terms of
24 who is a Marine and who is not a Marine.

25 But the Marine Corps has some unique

1 missions. They always like to point out that in
2 contrast to the Army, they are not an occupying
3 force. They call themselves an expeditionary
4 force. Their primary focus is on rapid assault,
5 the first ones on the scene, quick, fast-moving
6 missions, amphibious missions, of course, where
7 they come in from the sea from Naval ships. The
8 Marines like to consider themselves what they say
9 is the 911 force. That is, if there is a problem
10 call 911 in the world and you get the Marine
11 Corps. They can often be the first ones to go
12 someplace. And this is important because even
13 though readiness is certainly a concern in all
14 the services, in the Marine Corps -- much of the
15 Marine Corps not only feels they have to be ready
16 to jump on a plane tomorrow, but much of the
17 Marine Corps is actually forward-deployed at any
18 point in time. For example, there are a lot of
19 Marines in the Mediterranean right now and there
20 are others in many places around the world too.
21 So when you get into trying to do preventive
22 medicine things for the Marines, they don't feel
23 they have -- they often don't have time to do
24 things before deployment because many, as I say,
25 are on deployment currently.

1 The Marines certainly have had their
2 share of disease and non-battle injury over the
3 years. Just 3 of hundreds of potential examples.

4 In World War II, there were over 200,000 cases
5 of malaria in Naval forces in North Africa and
6 Southwest Pacific, primarily in Marine Corps
7 personnel. In the Gulf War, 57 percent of the
8 Marines surveyed had diarrhea, and of those, 20
9 percent were unable to work for one or more days.

10 In Somalia, one particular Marine Corps
11 battalion had a 24 percent attack rate of febrile
12 illness in just 5 weeks. That was primarily
13 dengue, malaria, and shigellosis.

14 I say that because even though DNDI is
15 well known to the Marines, for a variety of
16 reasons, though, when we went to war in the Gulf,
17 the preventive medicine infrastructure of the
18 Marine Corps was not very strong. And at that
19 time, there were in fact no preventive medicine
20 physicians assigned to the Marine Corps and much
21 of the rest of the preventive medicine staff, the
22 environmental health officers, entomologists and
23 so forth who went were junior and/or new to their
24 units.

25 Because of this experience in the Gulf

1 as well as many other factors, a few years ago
2 four preventive medicine officer billets were
3 created in the Marine Corps. I have had the
4 privilege of being the first one at headquarters
5 Marine Corps, and Captain Thomas back here was
6 the first one to go to III MEF in Okinawa. And
7 there are two others. Some of the other
8 preventive medicine specialties, for example, how
9 many environmental health officers there should
10 be in a Marine expeditionary force and such
11 issues, are currently under consideration.

12 The thought behind adding preventive
13 medicine officers back into the Marine Corps
14 structure is to get preventive medicine expertise
15 kind of on the scene with the Marines in their
16 culture, talking to them, wearing their uniform,
17 if they choose, and so forth. Because the
18 thought is this just makes a huge difference.
19 There is no way a Naval officer perceived as non-
20 Marine can be nearly as effective.

21 Some of the things we have done in the
22 last couple of years are the following. First is
23 a lot of work on some of the traditional
24 infectious disease issues, malaria prevention, I
25 heard about Japanese encephalitis, and other

1 things. We also, though, have been quite
2 involved in a program the Marine Corps calls
3 Semper Fit 2000, a play on their motto, Semper
4 Fi. And this is a 7 -- I think there are 7 basic
5 components to this program; stress reduction,
6 anti-smoking, reducing low back injuries, and
7 things like that.

8 Some of our preventive medicine
9 officers have also gotten involved, such as Dr.
10 Thomas, with a variety of occupational and
11 environmental health issues, safety issues, and
12 injury prevention issues, and I think one of the
13 things that the preventive medicine officers have
14 brought to the Marine Corps is a lot of kind of
15 expert advice on what the Marines should do in
16 operations other than war. Actually, the Marine
17 Corps term is actually other expeditionary
18 operations, but I think you know what I am
19 talking about -- refugee crises and so forth.

20 Some of the, I think, more interesting
21 projects of note that I and some of my colleagues
22 are currently involved in, just to show you a few
23 other things we are doing, are one project we are
24 extensively involved with right now is working on
25 the medical section of country handbooks. May I

1 borrow yours here for a second, Mike?

2 I don't know if you have all seen
3 this, but this is the Bosnia country handbook.
4 Over 100,000 of these have been printed and they
5 tell me have been distributed to virtually
6 everybody who is in Bosnia or may be involved in
7 Bosnia. And to summarize a long story, the
8 medical section in here has really kind of been
9 patched together and kind of jury-rigged in the
10 past. One thing I and some of my colleagues from
11 the other services are working on is how to make
12 this a very effective preventive medicine
13 section.

14 Another project we are working on is
15 trying to help the line Marine Corps deal with
16 suicide. It is not clear that the Marine Corps
17 has a unique suicide problem. However, the
18 senior leadership of the Marine Corps certainly
19 think they may have. And there is a tremendous
20 interest in trying to define better risk factors
21 for suicide in the Marine Corps and what
22 intervention should be made.

23 The Marine Corps has tremendous early
24 attrition. And that is to me the astounding
25 number of between 30 to 40 percent of Marines who

1 enlist never complete their first tour of duty.
2 So needless to say, the Marine Corps has
3 tremendous interest in figuring out why that is
4 and trying to do better. I think we in
5 preventive medicine have helped a lot in trying
6 to sort out what is going on. I don't plan to go
7 into these things in great detail, but as you can
8 imagine it is for a wide variety of causes, many
9 medical. Anyway, I think we have helped them a
10 lot to sort his issue out.

11 Another issue we have gotten involved
12 in, as have some of the other service preventive
13 medicine people, is an issue of asthma and
14 suitability for active service. And the question
15 here is how the military determines who is
16 physically fit to come in the service and not.
17 And many of the rules it doesn't take much data-
18 based evidence to decide. I mean, if you are
19 missing a limb, you are clearly not suitable for
20 active service. But many issues, such as if you
21 had asthma as a child should this preclude you
22 from coming on active duty, are very difficult
23 questions to answer, and I think we have brought
24 kind of a public health or epidemiologic
25 perspective to this that has helped to sort this

1 out.

2 And the last project I want to mention
3 is something called the chemical/biological
4 incident response force. This is a project that
5 is being driven by an Undersecretary of the Navy,
6 Dr. Danzig, and the Commandant of the Marine
7 Corps. They believe that the Marine Corps should
8 develop a capability to respond to terrorist
9 incidents in the Department of the Navy and
10 Department of State facilities worldwide. And
11 this is still in the development phase in what is
12 called the combat development process, but
13 preventive medicine has been extensively involved
14 in trying to work with the line in what such a
15 force could reasonably be expected to respond to
16 and how it ought to be configured and so forth.

17 So, again, thank you for the
18 opportunity to speak to you, and I hope that
19 gives you a little background on preventive
20 medicine and epidemiology in the Marine Corps
21 today.

22 COLONEL FOGELMAN: Questions? Thank
23 you.

24 DR. KULLER: You are looking into the
25 reasons for the attrition?

1 COM. SHARP: Yes.

2 DR. KULLER: That is interesting,
3 again, because those go back many years. Because
4 I remember 30 years ago we tried to look into
5 that when I was with the Marine Corps for a
6 while. There is a very high attrition also of
7 young marine officers as well as -- at least in
8 those days, as well as enlisted men. I don't
9 know whether that is still the case. But even
10 among the officers, there was a high attrition.

11 COM. SHARP: I don't think it is as
12 high with the officers. And, of course, the
13 Marines like this because they want to weed out
14 the -- but 30 percent is a little excessive.

15 DR. FLETCHER: I also was with MCRD
16 for two years, and I was a Navy -- they would not
17 let me wear a Marine uniform for some reason. I
18 guess I didn't cut my hair properly.

19 COM. SHARP: Well, that is one of the
20 hazards. You go to Marine barbers.

21 DR. FLETCHER: But my comment is that
22 at that point we had three psychiatrists on base,
23 at the MCRD, and an enormous number of kids we
24 had who just asked to leave the military. Is
25 that still a major problem or has that been

1 better recruited in the recruitment area?

2 COM. SHARP: No. That is currently a
3 big issue, clearly one of the major causes of
4 this early attrition. There are a lot of issues
5 there. Because the recruiters, of course, are
6 under tremendous pressure to get people in, and
7 there are a lot of questions as to whether they
8 are getting people in who could be well
9 identified ahead of time as not being able to
10 make it. And there are a lot of questions about
11 can you make a Marine without a lot of these
12 people falling by the wayside. A lot of these
13 people may be salvageable, is what I am saying.

14 DR. FLETCHER: So it is still a major
15 problem.

16 COM. SHARP: Yes, sir. Definitely.

17 DR. KULLER: Colonel O'Donnell.

18 COLONEL O'DONNELL: Now that the
19 Marines have taken this beach, I can come in and
20 occupy it for a little while. But I won't occupy
21 it for too long. You have heard plenty already I
22 think from Colonel Defraites about one of our
23 major preoccupations, which is what is going on
24 in Bosnia. So I am just going to touch on some
25 topics very briefly and then get out of the way

1 for whoever we turn it over to, I guess it is the
2 Air Force.

3 These are a couple of topics I want to
4 talk about. As you've heard earlier today,
5 Colonel Defraites touched upon the issue of
6 deployment surveillance, and that is a biggie and
7 I won't belabor that point. However, we also
8 have a longer range dream that we will be able to
9 eventually integrate our handle on what happens
10 during deployment and integrate that into getting
11 a handle on what is happening to all of us all
12 the time, even when we are in garrison. We
13 really don't capture that at the moment, and that
14 is a dream. Perhaps making that happen is
15 dependent upon the actual arrival of what at the
16 moment are some sort of clinical information
17 systems. We will actually capture medical events
18 in a real time basis and they will actually end
19 up in a data base that we can tap into and find
20 out what is happening with our population.

21 I put the anthrax vaccine
22 implementation plan in there simply -- this is
23 almost a follow-on to what the Board has
24 previously considered and made some
25 recommendations to DoD about this. The board in

1 the past has basically said the military should
2 consider the use of the vaccine or recommended
3 the use of the vaccine to cancel the biological
4 warfare threat, and things have reached the stage
5 now where the Army as the executive agent has
6 essentially been asked to deliver an
7 implementation plan to the Department of Defense.

8 I won't get into any of the details, but as you
9 can imagine you can't do this like this because
10 it is a six-shot series in the vaccine series,
11 and of course it is for a contingency threat and
12 there are a lot of complicating scientific as
13 well as some practical issues on doing this.

14 But that is a very hot topic that is
15 very hot actually because there is urgency right
16 now because the budgeting cycle is about to close
17 and the request for the next fiscal year, really
18 the out years, are really due now. So folks have
19 really got to come up with a plan so they can
20 estimate costs to see whether or not that can
21 actually be resourced.

22 The next item, medical readiness of
23 the reserve component -- this is actually a
24 narrow Army issue, and I thought a lot about Dr.
25 Ascher as I was putting this note down here

1 because I know he has got a great deal of
2 interest in what happens in the reserve
3 component. And this is really kind of an
4 interesting side bar because it relates to some
5 of our topics or discussions earlier today where
6 people were talking about the nature of what
7 kinds of periodic medical evaluations people
8 should undergo.

9 Well, the Defense Authorization bill,
10 which was just signed, contains a provision, and
11 it is about 15 lines perhaps, which basically
12 requires the Army to do the following for those
13 elements of the reserve component who are, I
14 guess you would call them, sort of the folks who
15 might deploy early in the case of mobilization.
16 And basically it calls for an every other year
17 physical evaluation for those members of the
18 reserve component who are over age 40. It does
19 not say what kind of evaluation that might be,
20 which may be our loophole. But in fact, that
21 frequency is a whole lot better than the active
22 component gets, which generally right now is an
23 every 5 year requirement.

24 The other interesting thing is that it
25 requires that these people who belong to the

1 subset of the reserve component will get an
2 annual dental examination. Although up to now
3 reserve component are basically not entitled to
4 dental benefits normally, but now we have
5 actually mandated to provide an annual dental
6 examination. And it looks like, if there are any
7 real serious problems in terms of their dental
8 health that might render them non-deployable, we
9 may actually also have to provide them the care,
10 which will rehabilitate their dental health.

11 So that is an interesting -- and there
12 are some folks right now trying to figure out how
13 are we going to do this, and again they are
14 trying to rush an ability to provide for this
15 into the budget cycle once again. So some
16 decision about how we are going to do this is
17 being rapidly considered. And I think because of
18 the fact that some of these requirements are
19 actually more intensive than the active component
20 gets, people are also looking for some loopholes.

21 Lastly, just as a first announcement,
22 the Army Preventive Medicine Symposium, which is
23 primarily a physician's symposium, is scheduled
24 for Charlotte this coming September.

25 Just a couple of other brief items for

1 those who may not be aware. This is the numbers
2 of the assets we have in the Army in preventive
3 medicine and occupational medicine physicians.
4 And fortuitously, the total number of bodies who
5 are working in that field adds up to 84, which is
6 exactly the same number of slots that we have in
7 the force structure. There is a little bit of
8 mismatch there, but that is okay. We consider
9 ourselves interchangeable. So right now, we seem
10 to have all the bases. covered.

11 I just throw that up to give you an
12 idea of the magnitude of the physician types of
13 assets we have in the preventive medicine arena.

14 Because related to that are some considerations
15 in graduate medical education. Now just to
16 reiterate, we have three residencies in the field
17 of preventive medicine and occupational medicine
18 in the Army. One of them is situated here, one
19 of them is at Madigan out at Fort Lewis in
20 Washington, and then we have the occupational
21 medicine residency at what we call the CHPPM.
22 Each of those has three slots normally, three
23 training slots per year.

24 The occupational medicine residency at
25 the CHPPM is actually going to cease operations.

1 And what we are going to do essentially is to
2 continue the tradition of training physicians in
3 OM at the Uniformed Services University. They
4 have had an existing training program there in
5 occupational medicine with slots for Army
6 physicians, but we have not taken advantage of
7 that in the past because we had our own
8 residency. But for a variety of reasons which I
9 won't go into, in essence we have decided to put
10 our eggs in that basket in terms of occupational
11 medicine training. I think one of the reasons
12 that kind of clinched that decision was a sensing
13 that the Uniformed Services University was no
14 longer quite so acutely threatened with closure.

15 It appears now to be a viable institution --
16 notice I said appears now to be. I really don't
17 know what the future will bring, but the serious
18 threats appear to be going away.

19 In this, just at the end of November,
20 we selected 9 candidates for those 9 slots in the
21 residency programs. Unfortunately, 3 of those
22 selectees have subsequently declined to attend
23 this coming year for a mixed bag of reasons. And
24 so we are going to have three vacancies, one in
25 each of the programs. Unfortunately, the Army is

1 not interested in giving us the option to hold a
2 second look or a standby board to consider other
3 candidates. That is a no. And it is not just
4 for us. It cuts across all of the GME programs
5 in the Army.

6 And I bring that up simply to give you
7 some sense -- and again, I am not going to get
8 into details. But graduate medical education in
9 the Army is faced with two challenges in the
10 near-term. One is simply it is downsizing. It
11 is a gradual downsizing, but it is a real one.
12 There are efforts to integrate programs between
13 the services, for example the programs here at
14 Walter Reed are essentially trying to integrate
15 with the programs over at the National Naval
16 Medical Center at Bethesda which is four miles
17 from here or something like that. Both major
18 medical centers. And the residency program down
19 at Malcolm Grow Air Force Hospital. And
20 similarly in San Antonio there is an initiative
21 to do that. Those initiatives are not directly
22 touching the preventive medicine residencies, but
23 they are in part an attempt to achieve some
24 efficiencies and economies of scale within DoD at
25 large.

1 More importantly, there is actually
2 serious discussion and question within the ranks
3 of DoD and probably outside as to whether or not
4 the Department of Defense should conduct graduate
5 medical education at all in any way, shape, or
6 form. And I guess the alternative is basically
7 we will simply buy specialists who have been
8 trained on the outside or will recruit folks but
9 have them trained on the outside through some
10 sort of agreements with the civilian sector. I
11 guess that is the other end of the spectrum.

12 I think most people in the Army
13 medical department and probably in the other
14 service medical departments really are not too
15 thrilled with that end of the spectrum. And I
16 guess to sum it up in a nutshell, we basically
17 consider the GME as sort of the lifeblood in the
18 Army's case of the Army medical department. And
19 without our own training programs, we will never
20 be able to buy quality people from off the
21 streets. We simply -- they are not out there. I
22 sort of occasionally conclude my discussions of
23 the topic with if you are a physician in the
24 civilian world and you have just finished your
25 specialty training, why in the world would you

1 join the Army. That is sort of the last thing, I
2 think, that people would be thinking of. And I
3 think we don't have some of the more cogent
4 incentives we had 20 years ago when we drafted
5 people or threatened to draft them.

6 So I think breeding our own not only
7 gives us an opportunity to continue to recruit
8 and retain quality people, but also enables us to
9 sustain quality. I am told that some of our
10 quality and competency problems we have had,
11 within the Army at least, are disproportionately
12 occasioned by folks we've taken in off the street
13 that we haven't trained ourselves. So that is
14 kind of an issue that is very sensitive within
15 the Army medical department in general. Right
16 now preventive medicine is not suffering from
17 that challenge, but I think we will probably ride
18 that same boat depending upon how things go.
19 Those are the only topics I wanted to bring up
20 because you have heard plenty from us already.
21 Any questions?

22 DR. ASCHER: You mentioned the reserve
23 component. I think if you would ask from the
24 other perspective how many reserve medical
25 officers have been recruited in the last year, I

1 think it is about the same number you mentioned,
2 very few. The same problem about taking off the
3 street. The number was astonishingly low. The
4 number that were lost after the Gulf War, of
5 course, was astonishingly high. So we have a real
6 problem.

7 The issue of the 2-year physical, as I
8 would see it, is the issue of trying to retain
9 readiness in a force that you really don't
10 monitor their medical status. And I think the
11 experience in the Gulf War was when you put
12 reservists up, the rate of people that don't pass
13 the physical at the time of deployment is very
14 high compared to active duty. And you have no
15 way to track -- this is people who's care is all
16 on the outside. So you want to be able to keep
17 their deployable status in hand. But yet you
18 don't have any access to what they are doing in
19 terms of their diseases that are occurring. And
20 the way you try to do that is by an every other
21 year physical. I don't think that is going to
22 work.

23 That is another case for maybe
24 offering medical benefits to try to capture that.

25 And then when people have illnesses, put them in

1 the right category of profile and then have a
2 really ready force. It is tight out there. They
3 are trying to get rid of the dead wood, and this
4 is an approach, but I am not sure it is best one.

5 COLONEL O'DONNELL: And you mentioned
6 possibly offering medical benefits to the reserve
7 component. To the extent that the reserve
8 component has problems recruiting and retaining
9 people, any of them not just the medical folks.
10 If prospective joiners of the reserve component
11 were led to believe that there would be a medical
12 benefit associated with their joining up, that
13 might be an incentive to people. It might not
14 be. I really don't know. But certainly it is
15 not an issue right now. They are not our
16 beneficiaries except when they are on active
17 duty.

18 COLONEL FOGELMAN: Any other
19 questions? Thanks.

20 DR. KULLER: Colonel Parkinson?

21 COMMANDER PARKINSON: Back to Vegas.
22 In the spirit of joint operations, let me try to
23 put together what I have heard so far. After the
24 Navy gets well enough to leave port, the Marines
25 take the beach, the Army occupies the beach, then

1 the Air Force arrives to enjoy the beach. But we
2 take our sunscreen and our DEET. I will tell
3 you, Dr. Kuller, we are prepared.

4 Now, Dave, I don't know what the Coast
5 Guard is doing for us off shore, but hopefully
6 keeping the beach safe.

7 COMMANDER ARDAY: We clean up the oil.

8

9 COMMANDER PARKINSON: We've got this
10 act together. I'll tell you, the services are
11 together. We wanted to cover a couple of things
12 here quickly that have developed in the last
13 three to four months and really represent about a
14 year and a half or two years of hard effort on
15 both the science and the policy standpoint to
16 bring together, and that is the Improved Fitness
17 Program and Health and Wellness Centers, a
18 project that we call EEpICAM. The health of the
19 Air Force and the Air Force medical service, to
20 expand a little bit on some of the things that
21 Dave talked about, and HIV issues as they
22 currently exist in the fall-out from the
23 legislation that was just passed.

24 Dr. Fletcher was instrumental in
25 helping us about a year and a half ago in

1 reviewing the science base of using submaximal
2 cycle ergometry to estimate VO2 Max as a tool
3 to improve force fitness in the Air Force. And
4 at that time, we had used the University of
5 Florida, Dr. Michael Pollack, Center for Exercise
6 Science to validate and find the strengths and
7 weaknesses of the variation of the Ostrin-Ryding
8 protocol that we had used for submaximal cycle
9 ergometry testing.

10 We incorporated those recommendations
11 into reissuing of the software and kicked off a
12 new program on the first of January of 1996 with
13 extensive briefings to the Air Force chief of
14 staff and the senior listed advisors in preparing
15 for this. It was a very exciting time because it
16 is rare that you can see a major force program
17 move forward to incorporate the science, the
18 policy, and the logistics in the way that this
19 program has. We still have bumps in the road.
20 There is no question about it.

21 But I have placed this program similar
22 to where the NCEP might have been 10 or 15 years
23 ago when they thought about trying to stress that
24 everybody knows your number. And I think as we
25 learn more about what VO2 Max is and how it

1 correlates with indices of health, that knowing
2 your VO2 Max score is something that we are going
3 to talk about down the road as a way to improve
4 and measure your own level of aerobic fitness.

5 As such, we eliminated the way we
6 express the scores. It was in broad categories.
7 There was a category 1, 2, 3, 4, 5, and 6, and as
8 I said to people, I don't tell you that your
9 blood pressure is category 1 or that your
10 cholesterol is category 4, you know the absolute
11 numbers. And then you know the relative
12 percentile ranking of where you are with respect
13 to people in your sex and age group.

14 We have also committed to having
15 exercise physiologists. We have got the
16 authorization now to hire one of those at every
17 single base who will oversee our program and
18 serve as a consultant to the commander as well as
19 the exercise counselor for the individual members
20 as they try to improve their cardiorespiratory
21 endurance.

22 General Fogleman, the Air Force chief
23 of staff, said the problem with this program is
24 not as much the science, it is the marketing and
25 education. If there is one theme that runs

1 through this meeting today it is that we spend a
2 lot of money and a lot of good brainpower on
3 developing programs and initiatives, new
4 products, vaccines, and yet they fall flat on
5 their face. I am overstating it a bit, but
6 certainly we need to get more savvy about
7 marketing. And he basically turned to the
8 Surgeon General and said, you know, I have a lot
9 of filters around me as a four star chief of
10 staff, but he said when my driver in my car turns
11 around and says, hey boss, what about that
12 bicycle test, you know it has got to be
13 concerning him. We don't understand it. We don't
14 know what VO2 Max is. Tell me why it is
15 important?

16 So basically we are in a major
17 marketing blitz right now using both the medics
18 and the line resources to do that. And I would
19 suggest what I am trying to learn from this is
20 how can we use this type of marketing approach
21 for things like personal protective measures and
22 other things. I see a lot of Air Force heads
23 nodding here, but we are trying to relearn how to
24 work our own system so that we get out education
25 and behavior change.

1 But a standardized briefing was
2 developed for all commanders and commanders call
3 and for hospital commanders to brief all medical
4 personnel. We don't get any training in medical
5 school on such things as exercise testing, VO2
6 Max estimation, or really on disease prevention
7 and health promotion, and that is really what we
8 are talking about here.

9 And finally, the cornerstone of this
10 is the integrate of what we call a Health and
11 Wellness Center. This started, as you know,
12 approximately two years ago when the then head of
13 the Department of Personnel of the Air Force went
14 around to various Fortune 10 companies and said,
15 you know, the Air Force is a Fortune 10 company.
16 Why is it we can't offer our people the same
17 thing that the people at Xerox have or the people
18 at USAA have for their people to improve their
19 health and fitness. And that was the origin of
20 the Health and Wellness Center.

21 We see it as a continuum from the
22 medical treatment facility to the Health and
23 Wellness Center to the fitness center. And as
24 people enter our system, they may already be
25 healthy but what they've got to do is use the

1 services of a Health and Wellness Center with an
2 exercise physiologist, nutritionist, dietician,
3 smoking cessation, or whatever it is so that they
4 don't have to access that MTF. So that our
5 periodic examinations are targeted at the MTF,
6 but we use that Health and Wellness Center as an
7 extension of the clinic. It has got a classroom.
8 It has got centralized cycle ergometry
9 assessment, and also those resources as I just
10 identified.

11 The core personnel is a health
12 promotion manager from the MTF. The exercise
13 physiologist comes from Air Force Services, which
14 is that area which is responsible for the fitness
15 center, and two technicians and line and SG
16 matrix of money. And what is important about
17 this is Secretary of the Air Force Widnall and
18 the Chief of Staff Fogleman signed out both of
19 these programs simultaneously in the last week.

20 It was a wonderful Christmas present for the
21 Surgeon General after working on this for two
22 years. So the logistics, the rational and the
23 science all go together. Now we have to move out
24 on it.

25 We have mobile training teams

1 consisting of four individuals from our fitness
2 program office in San Antonio that are visiting
3 every single Air Force base over the next six
4 months meeting with the wing commander and the
5 hospital commander and anybody else who wants to
6 meet with them, the senior enlisted advisors, to
7 talk about these programs, to talk about how we
8 measure, what we measure, and why we do what we
9 do. In that regard, we are also working very
10 much with the Public Affairs Office at the
11 Pentagon in terms of a media blitz as it relates
12 to this.

13 We are very excited about these two
14 initiatives because it allows us to basically
15 take a comprehensive approach to health as
16 opposed to just an episodic treatment of illness.

17 I talked last time also about the
18 notion that the resourcing schemes that we have
19 been using within the Department of Defense and
20 certainly within the Air Force have been what I
21 would call under Medicare UCR, usual, customary,
22 and reasonable, and then you adjust it by plus or
23 minus percent or plus or minus people. And what
24 we have been trying to do is to build into our
25 resourcing scheme an epidemiologic and economic

1 perspective as it relates to resource allocation
2 such that we can make some evidence-based
3 decisions. And since the time I last spoke with
4 you, we have basically gotten together through
5 the Office of Prevention and Health Services
6 Assessment and a contractor a project that we
7 call EEpICAM, which is Economically and
8 Epidemiologically Integrated Cost Assessment
9 Model.

10 What we are doing is reviewing off-
11 the-shelf products that are currently available
12 in essentially a run-off, and we are then going
13 to tailor-make and if you will, blue them with
14 Air Force specific data to look at return on
15 investments using both direct medical costs and
16 indirect costs as it relates to return on
17 investment for utilization management programs,
18 health promotion and disease prevention programs,
19 any number of interventions that are out there in
20 the literature.

21 Now Dr. Fletcher showed you today that
22 a smoker costs Tenneco or Exxon or somebody
23 \$1,100.00 a year. It is not medical care
24 dollars. It is indirect dollars. And one of the
25 problems that we have within DoD, as I might have

1 mentioned before, is that we have no incentive on
2 the SG side of the house as the corporate medical
3 director of IBM does to save IBM's profit bottom
4 line. We do it in terms of readiness, but it is
5 still kind of squeaky. One of the things that
6 this project is going to try to articulate to the
7 Air Force chief of staff is that we are costing
8 you money as your medics by not putting state of
9 the art health promotion, disease prevention,
10 utilization management, case management, disease
11 management programs in place. And we can quantify
12 the delta, if we did these programs right, that
13 we would be able to save you.

14 But the key to this, and my key, is
15 that this model called EEpICAM, the I could stand
16 for a lot of things, integrated, informed,
17 intelligent, but it could also be irrelevant.
18 Because if we do not win the argument that the
19 medics have a stake in the indirect cost to the
20 Air Force, just as every other Fortune 500
21 company does, there is really no reason to talk
22 at all really about health promotion and disease
23 prevention if I am turning over 30 to 40 percent
24 of my people a year and the average tenure is one
25 term.

1 So I think this is a critical,
2 philosophical, conceptual approach that we have
3 got to begin to adopt, and I think we would have
4 had it years ago if the DHP wasn't run separately
5 as a separate budget. And basically if they had
6 to make a choice at the command level between
7 buying bullets or paying for health care, the
8 commanders don't have to make that choice because
9 the budget they perceive as a different pile of
10 money.

11 The other thing that we are doing is
12 we are trying to spin up the Surgeon General
13 policy staff on epidemiology and economics. As
14 we realize, we make decisions every day to the
15 tunes of millions of dollars in our office, many
16 with little or no data, and the data that we get
17 there is not systematically collected and it is
18 not scrubbed in terms of looking at what is the
19 quality of it.

20 So to that end, we are holding a
21 Surgeon General's off-site for two days with
22 about 70 of the SG senior staff in which we are
23 going to give a primer on epidemiology and cost
24 effectiveness methodologies. So that terms like
25 positive predictive value, screening tests and

1 cost effective are not thrown around loosely.
2 That people know at least the terminology. They
3 know what they don't know when they come to
4 evaluating the next packet that comes up that
5 talks about a new program or elimination of an
6 existing one.

7 To that end, we have had several
8 principles in terms of how we want to reflect on
9 the health of the Air Force and on the health of
10 the Air Force medical service. And that is --
11 our principles are very simple. Plagiarize,
12 plagiarize, plagiarize, standardize, and compare
13 to what is out there rather than create de novo.

14 And to that end what we have done is the
15 worldwide survey which Dave mentioned is a very
16 useful instrument. As of right now, it comes out
17 once every three years. And we are saying that
18 for the purposes of program planning we need
19 something as a quicker scrub, more than that, on
20 an annual basis.

21 And as such, we have just completed
22 the Air Force 51st state, if you will, CDC
23 behavioral risk factor survey using the exact
24 same methodology, a telephone survey, of
25 approximately 2,000 Air Force active duty

1 members. And we are committed to do that on an
2 annual basis. So at any rate, we have that.

3 We also have a 5-year morbidity,
4 mortality, and disability study which has been
5 completed. All of these will be presented to all
6 our MAJCOM surgeons on Monday on a worldwide
7 video teleconference and disseminated to them to
8 begin to be used for program planning purposes.

9 In addition, when we bring together
10 some 300 people, 5 representatives or so from all
11 of our MTFs around the world, we will be
12 presenting the health of the Air Force and the
13 Air Force medical service, turning these data
14 into some programmatic initiatives and some
15 resource allocation types of things that could be
16 very useful. But we are right now, as we define
17 the primary care platform of how the system
18 should work, what services should be developed in
19 a HOC and not in the doctor's office, how do we
20 make sure that the clinical preventive services
21 are delivered, and how do we make sure that we
22 are not iatrogenically treating things in the
23 clinic that shouldn't be there in the first
24 place? All of these things are linked together
25 and we see that conceptually as such.

1 So the business plan which we are now
2 developing in the Surgeon General's office will
3 speak to doing all of those.

4 The final point I want to talk about
5 is the HIV issues. The Air Force was designated
6 by Health Affairs to be the point of contact or
7 executive -- sometimes they say executive agent.

8 I think you might call it executive stuckee for
9 the issue of should we look at consolidating all
10 HIV testing under either a single contract or
11 bring it all in-house, and if we should, is the
12 methodology of doing the HIV test all the same
13 across the service?

14 Well, basically the Air Force convened
15 the working groups of both laboratory people and
16 preventive medicine folks and stated that as
17 these contracts come up to be expired, there will
18 be an analysis of the make-buy decision by an
19 independent audit and with that basically we will
20 move towards consolidating HIV testing in the
21 three services.

22 Related to that is, of course, the
23 deployment surveillance and the serum bank. The
24 Army/Navy serum bank includes any Air Force
25 personnel who came in through the MEP station,

1 which is the military entrance processing
2 station. But it does not include HIV negative
3 sera drawn on officers. We have just not kept
4 it. And we have done our in-house sera on
5 individuals down at the epidemiology division
6 since the onset of the program. The sera is now
7 being retained. It basically means that for the
8 17 percent of the Air Force that is officers,
9 that essentially we would have -- you know, they
10 may not have come in through a MEPS, and
11 therefore we don't have a specimen on them. But
12 for the 83 percent roughly of the enlisted, we
13 certainly have them in the sera bank already.

14 So we are closing that loophole, if
15 you will, and evaluating the program options as
16 to whether or not we should just send all our
17 sera to the Army/Navy joint DoD sera bank or
18 whether or not we should do it in house. There
19 is not a single decision, I will tell you, that
20 is not being scrutinized right now by the Surgeon
21 General's office as to what is the most
22 economical way to get the same job done.

23 We are going through a radical in-
24 house analysis right now. It is very painful
25 looking at up to a 30 percent cut across the

1 entire Air Force medical service and personnel.
2 When and if that cut comes, we want to be
3 prepared to say how can we preserve the mission
4 of the Air Force medical service, which is
5 basically to support our fliers and our active
6 duty members.

7 And finally, let's leave the least
8 controversial for last, is many of us here have
9 been very, very busy working the legislation
10 which appeared in the recently passed bill that
11 said all HIV positive members will be separated
12 within 6 months of the passage of the signing of
13 that legislation, which puts it at 31 August
14 deadline that all current HIV members. That is
15 approximately 1,000 individuals on active duty.
16 I understand the Air Force is relatively small.
17 But there has been a high level working group at
18 DoD working on both presidential concerns as well
19 as personnel medical coverage decisions, et
20 cetera. Hidden underneath -- this is just a
21 camel's nose in the bigger tent of the issues
22 that Trueman talked about earlier of asthma and
23 retention in the military. The whole issue of
24 retention standards. Should anybody be retained
25 who is not physically able to deploy at a

1 moment's notice worldwide, which really this is a
2 surrogate issue for, I would personally contend.

3 So that is kind of in there. But unfortunately,
4 the clock is ticking and there really is just six
5 months for DoD to get its act together vis a vis
6 this issue.

7 So we will stay tuned in the Air
8 Force, as I think in the other services. It
9 really is not a medical issue at this point, it
10 is a personnel issue. And as such, we coordinate
11 with the Air Force DP as they move forward on
12 this very contentious subject. So that is all I
13 have, Dr. Kuller.

14 DR. GWALTNEY: Mike, since I have been
15 on the board, I have admired the energy and the
16 effectiveness you have brought to this practice
17 of health promotion and from the Air Force. But
18 you said one thing, and I may have misunderstood
19 it, but I think it was to the effect that if you
20 can't show that you are saving money, we don't
21 have anything. I am not sure I am quoting you
22 right. It came across that way to me. I don't
23 think you really mean that. I think the other
24 reason you are doing it is because it is good for
25 the people in the Air Force. It is good for the

1 men and women in the Air Force. If you stop
2 somebody from smoking, it is good for that
3 person. And that is what being a doctor is all
4 about. And I just think that is very important.

5 And I think the Fortune 500 companies have
6 probably fallen into the same trap. The
7 employees have great skepticism. I think in the
8 political arena today and the presidential
9 campaign, we see this hostility in our medical
10 center and the people in our wellness program.

11 They say, oh they are doing it because the
12 university wants to save money. They don't care
13 about me. And I think we have got to be careful.

14 Because we are not doing it just for that. We
15 are doing it for other reasons. And I think
16 maybe then people would be more willing to take
17 the insecticides, to wear the clothing, and to do
18 all that if they realize this also is for their
19 own good. I just want to make that point.

20 COMMANDER PARKINSON: I absolutely
21 agree. I apologize if I sometimes come down too
22 quantitative on the economic side. I guess this
23 is like talking inside the church, and I assume
24 everyone here is bonded with the same religion of
25 doing it for the right reasons, and that is make

1 people healthy, quality of life, morbidity, and
2 mortality. But I would tell you, just as in the
3 marketing, the reason is that if there is any
4 group or perspective in medicine that could
5 really make an argument that would help make the
6 day, is basically for those of us who are trying
7 to talk about why it is important to stop smoking
8 is to martial the economic argument in a more
9 effective way. I think the relative tone of the
10 way it came out is unfortunate, but I think right
11 now I will tell you -- I will be very honest with
12 you. We have hospital commanders out there who
13 basically the very first thing they will get rid
14 of is a smoking cessation program. The very
15 first thing they will get rid of is a nicotine
16 replacement therapy program because patients want
17 to get over-the-counter drugs for their URIs.

18 Now one of the issues that we came to,
19 we realized that basically there is such a lack
20 of incentive, aside from the verbiage we give
21 about readiness, on prevention that the Air Force
22 Surgeon General -- and we really don't have a
23 capitated care system yet under Tri-Care, that
24 the Air Force Surgeon General said I am putting
25 fire walls around 25 million dollars and you can

1 only use it for prevention. You cannot use it to
2 hire more people to work in the ICU or whatever.

3 And I think that responsibly making this
4 argument is something I am trying to do. I might
5 have come on too strong.

6 DR. GWALTNEY: Well, we've got to win
7 the argument with the money people, but we've got
8 to win it with the hearts and minds of the people
9 too that are being affected, and that is the way
10 we will really wind the battle in the long run, I
11 think.

12 DR. FLETCHER: Mike, as well as the
13 company's are doing, do you think you are getting
14 through your Air Force personnel into their
15 families or their dependents? Do you think they
16 are feeling an impact with this yet, or is that
17 too early to say?

18 COMMANDER PARKINSON: Well, the major
19 theme of Secretary Widnall is to improve the
20 quality of life in the Air Force, and I think the
21 things that we are doing, we are basically trying
22 to link very closely with the family advocacy
23 programs, things that we have not traditionally
24 thought of as really medical stuff. Family
25 advocacy and other types of things on base --

1 youth programs, daycare center programs, all
2 those types of things. And when you start
3 getting in that sticky wicket of spouse and child
4 abuse, which is out there in DoD, those areas are
5 things we are trying to weight in in terms of
6 this notion of building a healthy community. It
7 is not easy because there is not a lot of good
8 data from my perspective on what works and what
9 doesn't. But I think we are making a foray into
10 it.

11 DR. FLETCHER: Just a point of
12 information. The Surgeon General's report on
13 physical activity and the importance thereof is
14 going to be an enormous document that will be
15 coming out later this year. I have been reviewed
16 and others have for the American Heart
17 Association. This is going to be hand-in-hand
18 with a lot you are doing and others we are
19 thinking about here. It will be a very
20 compelling, large volume bill reference
21 recommendation from just another way to push the
22 importance of physical activity. It should be
23 out this year.

24 DR. ASCHER: Back to the HIV issue
25 for a second. I don't think anyone is here on

1 the board now that was here when they wrote the
2 original recommendations for the mandatory
3 screening program. There was a lot of careful
4 thought given when that was done that this was
5 linked to a policy for retention and evaluation
6 that was suitable for such a program and the two
7 fit together. And there is concern, at least
8 from some of the older members that aren't here
9 expressed to me, that doing a mandatory testing
10 program without informed consent in the presence
11 of an outcome which is dismissal is not going to
12 stand up in court. And there is some interest in
13 discussing it. So we have set some time aside
14 during the executive session tomorrow to meet
15 with the preventive medicine officers to sort of
16 talk about this.

17 Because we did have a role in this in
18 the past, not any of us here, but we want to make
19 sure we don't get left out here as a court case.

20 There was a suggestion, for example, that the
21 program be suspended until such time as the other
22 one is decided. Because it is potentially
23 something that would blow up as a case. I don't
24 think in law you can force someone to do
25 something that causes them to lose their job.

1 But that is just an opinion. We will talk about
2 it tomorrow.

3 DR. KULLER: Mike, could I ask you one
4 other question, and this may be totally
5 irrelevant. But there has been a lot of play in
6 the newspapers recently about some of the
7 accidents which have occurred in the Air Force
8 and the Navy with their airplanes. Has this had
9 any impact in regards to -- is this at all
10 related to human failure or has this had any
11 impact on your prevention or any kind of
12 behavioral aspects of this? Is this -- because
13 it certainly gets a very big play right now in
14 the newspapers in the civilian area, and you get
15 the feeling that something has gone awry.

16 COMMANDER PARKINSON: Well, we gave up
17 on the F-18 years ago. We didn't like it. Let
18 me just say from the Air Force perspective, there
19 have been some highly publicized and visible
20 aircraft accidents and also an incident at
21 Washington State with somebody who went on a
22 shooting spree. And just as Trueman said about
23 the suicide in the Marines, it is a public health
24 phenomena that rare events that get a lot of
25 media press drive not always good but sometimes

1 good outcomes. And I would say in both of these
2 aspects, the event of the individual who had a
3 psychotic break and went on a shooting spree has
4 driven a review of how the Air Force deals with
5 mental health and psychiatric conditions -- those
6 types of individuals. And certainly in the
7 aircraft accidents, it has been perceived not as
8 a medical or a mental health or any type of
9 issue, but a command issue. And the chief of
10 staff of the Air Force has had mandatory
11 briefings and times to basically say we take
12 officers seriously and we take command and
13 discipline very seriously. And I think it goes
14 very much along with some of the issues we've
15 talked about about compliance with personal
16 protection measures as let's not lose the beat
17 here in what we are doing. But I think beyond
18 that, that is about all I have to say. Dave?

19 CAPTAIN TRUMP: It is very similar for
20 the Navy. And on the medical side, we have our
21 aerospace medicine specialists, of which I am not
22 one, who certainly are much more conversant with
23 this. But this has -- up until the last few
24 months, it has been a good year. I mean the
25 overall trends have been continually down as far

1 as aviation accidents. But there have been
2 problems. They did do a stand down, I think, two
3 or three days of all the F-14 crews for
4 additional training for review. They are doing
5 the same thing over the next several months, I
6 think, for all the Pacific fleet aviation just to
7 make sure -- to go back and look at procedures
8 and make sure that they are doing the right
9 things. But there certainly has been interest.

10 CAPTAIN CUNNION: I think this is no
11 more different than cancer clusters. I think we
12 are getting involved in -- we are getting
13 randomness accidents and the press is building
14 them up.

15 COMMANDER SEIBERT: Specifically,
16 there was a request from Representative Ike
17 Skelton and the JAO did do an initial
18 investigation and data was provided by DoD which
19 demonstrated that the aircraft accident rates
20 have been continuing to decline in each of the
21 military departments over the last 10 years. So
22 that was given to the GAO and provided to Ike
23 Skelton and basically it was pretty much put to
24 bed at that point. I think what we have is high
25 profile events that when you are crashing

1 multiple airplanes every week, it is not very
2 noticeable. But when you bring your accident
3 crash rate down to where it becomes more of a
4 rare event, then it becomes more visible, and
5 that is where we are right now. The crash rates
6 are going so far down that they are becoming
7 visible when you hit a couple of clusters. This
8 is being viewed as a line commander accident
9 investigation type of problem.

10 COLONEL FOGELMAN: Thank you.

11 COMMANDER PARKINSON: Thank you very
12 much. DR. KULLER: Commander
13 Arday?

14 COLONEL FOGELMAN: If I could ask
15 while he is preparing if the board members and
16 the PM DOCs could hold for a few minutes after --
17 at the end of the meeting. I would like to have
18 a couple of seconds to address you, please.

19 COMMANDER ARDAY: Good afternoon. I
20 will start out by saying there haven't been any
21 outbreaks or other critical preventive medicine
22 issues in the Coast Guard in the past few months.
23 Our operational tempo has basically returned to
24 baseline after the Caribbean refugee surge that
25 we had in 1994. Most of our attention the last

1 few months has been on focused on structural
2 issues as the Coast Guard, like the rest of the
3 federal government, undergoes a contraction. I
4 will stand up here and correct Commander Sharp's
5 statement that the Marine Corps is the smallest
6 service. We are less than a fourth the size of
7 the Marine Corps at about 35,000 people and
8 getting smaller every day.

9 At last year's meeting, I did an
10 update on this and I thought I would repeat it
11 again. I talked about the summary of our annual
12 reportable disease notifications. The Coast
13 Guard has a fairly primitive, I will say,
14 compared to some of the other services now,
15 passive reporting system. It is based primarily
16 on individual disease cases of infectious
17 diseases, occupational illness or poisoning.
18 Besides the above individual cases, our
19 regulations require reporting of outbreaks of
20 illness that affect readiness or pose a threat of
21 contagion to other units or the community in
22 general and also epizootic or zoonotic diseases,
23 vessels placed under foreign quarantine, or any
24 other disease or illness or situation that might
25 be considered politically sensitive basically.

1 Since the system is entire passive and
2 the Coast Guard has a limited preventive medicine
3 infrastructure, under-reporting is, of course, a
4 significant problem.

5 For all of 1995, 37 disease alert
6 reports were received at Coast Guard
7 headquarters. One was for non-reportable
8 conditions, so we are left with basically 36
9 reports among 36 individual case patients having
10 37 reportable conditions. An additional
11 hepatitis patient was identified without an
12 actual disease alert report being received. So
13 those 38 disease cases were distributed as shown
14 in this pie chart. 21 percent were STD cases. 8
15 percent were HIV sero converters. 13 percent
16 were hepatitis cases, A, B, or C. 8 percent were
17 other GI illnesses. 21 percent were tuberculin
18 skin test conversions with no active cases of TB
19 reported. And 29 percent were various other
20 diseases including one case of dinghy fever, two
21 cases of viral meningitis, one case of tick-borne
22 rickettsial disease, and one case of Lyme
23 disease. There was one patient with both HIV and
24 syphilis who was counted in both categories and
25 one patient with both syphilis and gonorrhea who

1 was just counted once under the STD category.

2 This graph compares the case reports
3 received by category in 1995 with those in 1994.

4 There was an increase in reports from 27 to 38,
5 largely due to the increase in the tuberculin
6 skin test conversion and the other category that
7 you see here. We did beat the bushes some more
8 this year to try to drum up some more reports and
9 that probably increased our reporting rates more
10 than due to an actual change in disease
11 conditions.

12 If you look at our reports by patient
13 affiliation, and we do this because obviously the
14 immediate question are what are our rates rather
15 than simply our counts. We have here the 38 case
16 patients by organizational affiliation. 29 or 76
17 percent were active duty Coast Guard and the
18 remainder distributed as shown. Now we certainly
19 have fairly accurate denominator data for the
20 counts for the overall active duty Coast Guard
21 population. However, less than 50 percent of our
22 active duty population gets its primary care
23 within our clinic facilities. Probably 10 to 15
24 percent get their care at DoD facilities or
25 primary care because they are within catchment

1 areas for those facilities. And the rest, at
2 least 40 percent of the active duty Coast Guard
3 are outside both our clinic areas and DoD
4 collection areas or catchment areas, so they are
5 served by local civilian providers, many for
6 which we have standing contracts with, but
7 basically on a reimbursable fee-for-service
8 basis.

9 The latter population, of course, is
10 least likely to be captured by our reporting
11 system, unless of course they are identified with
12 something serious like HIV. For the rest of the
13 categories, the denominator served by our system
14 really haven't been accurately determined. We
15 have got some estimates, but they are basically
16 just estimates.

17 So if you take those and we do rates
18 here by 10^5 . If you want to do it, you can move
19 the decimal point anywhere you want if you want
20 to compare by 10^3 or 10^4 . But here we have our
21 rates over the entire active duty population.
22 Now with the exception of the HIV sero
23 conversion, actual cases and rates are probably
24 higher, again due to the under-reporting that I
25 mentioned. However, it should be noted that for

1 HIV, unlike the other services, the Coast Guard
2 didn't do -- I shouldn't say never because we
3 just did -- but didn't do periodic HIV testing.
4 I have mentioned that before at other meetings.
5 But only did initial testing and then clinically
6 indicated testing based on other STD, alcohol
7 abuse problems, requests, so on and so forth.

8 We just implemented routine periodic
9 HIV testing aligned with our quadrennial
10 physicals starting this past January. So I
11 expect HIV rates will rise somewhat over the next
12 year or so -- or next couple of years as we start
13 to get this going.

14 As for the question of whether -- I
15 will say one other thing because of the issue
16 that just came up about putting -- DoD now being
17 required to discharge people who come up HIV
18 positive. The Coast Guard has discharged people
19 that are HIV positive ever since the program was
20 implemented. We weren't covered by the original
21 DoD mandates to retain the people and so anybody
22 who comes up HIV positive is essentially given a
23 medical disability retirement. We don't have a
24 profiling system like the other services. People
25 are either considered worldwide deployable or

1 not. And if you are not deployable, you are
2 basically discharged.

3 Now we are hoping to get some
4 improvement in our surveillance system from our
5 CLAMS II implementation. CLAMS II stands for the
6 clinical automated management system. We have a
7 CLAMS I operating right now, but it really
8 doesn't catch any
9 -- it doesn't do any disease surveillance capture
10 or capture of disease rates. A new system is
11 being fielded starting later this year, we hope.

12 As the Coast Guard begins upgrading from our
13 existing 286 and 386 base standard work stations
14 running an operating system called CTOS, if any
15 of you have ever heard of that. It is
16 proprietary with Unisys. And we are going to go
17 to 486 primarily and some Pentium based machines
18 -- we are right on the cutting edge of
19 technology, running Windows NT.

20 Now the new software that we have
21 written in-house will capture ICD-9 codes for
22 each patient visit and patient encounter forms
23 which are filled out for entry will include the
24 most common ICD-9 codes and there will be look-up
25 tables there for anything else. So that should,

1 for the first time, really give us some much
2 better data -- capture much better data for
3 disease surveillance rates. And if an ICD-9 code
4 corresponds with a reportable disease, it will
5 automatically prompt the individual entering the
6 patient encounter data to create a disease alert
7 report.

8 This will greatly improve our
9 reporting rates, as I said, but we are probably
10 looking at calendar year 1998 or 1999 before it
11 becomes fully operational Coast Guard-wide.

12 Again -- of course this doesn't
13 entirely solve the problem of what we are going
14 to do for denominators, although we will
15 certainly have much more accurate denominators in
16 terms of clinic visits. And we can get fairly
17 accurate estimates of what our population is that
18 are served by those clinics. We do have that.
19 So from that we can probably do some
20 extrapolation Coast Guard-wide to get more
21 accurate estimates of rates.

22 As I mentioned, a lot of our concern
23 at headquarters in the last few months has been
24 dealing with the downsizing and streamlining
25 issues. Barring further cuts, the Coast Guard is

1 going to decrease in size by about 4,000
2 personnel or roughly 12 percent and reduce its
3 operating costs by 400 million dollars over 4
4 years, from 1994 to 1998. So we are right in the
5 middle of this now. These reductions are
6 categorized as either downsizing, which means
7 cuts without change in structure or mission, or
8 streamlining which involves reorganization. The
9 headquarters itself is undergoing what is called
10 a streamlining, which will result in a 20 percent
11 reduction in staff.

12 Now our office, the Office of Health
13 and Safety, is going to merge in a couple of
14 months with the office of personnel and training
15 plus the office of readiness and reserve to form
16 a new directorate of human resources in what
17 amounts to a major reorganization. And although
18 no medical professionals will be eliminated from
19 our office, a number of support personnel are
20 being cut, including almost the entire resource
21 management staff.

22 I am not sure what the implications of
23 that are yet although it may end up with those of
24 us who don't have a lot of resource management
25 training starting to wear resource management

1 hats and doing more of the day-to-day budgeting
2 and stuff like that.

3 Overall for the Coast Guard, these are
4 the actual medical billet reductions that have
5 taken place in the past 14 months. We have lost
6 one active duty physician billet. We are down to
7 55. And what is not included in that are the two
8 physician training slots that we have. So we are
9 down from 58 to 57 overall. We have lost two
10 active duty dentist positions, one active duty
11 physician assistant position, and a number of
12 technicians or enlisted health services
13 personnel. 9 in actual terms of clinical
14 providers, and some of those 34 active duty
15 medical administration people are senior enlisted
16 folks that are in the HS rating. So overall we
17 have lost 51, and then there are going to be more
18 cuts to come because these don't include the
19 headquarters cuts and stuff that are actually
20 going to occur in the 4th quarter of this year --
21 or 3rd and 4th quarter of this year and perhaps
22 somewhat into next year.

23 The last thing I was going to talk
24 about is a project that I have been involved in
25 personally because it has consumed a fair amount

1 of my time in the last few months. And I think
2 it has some implications for some of the issues
3 that the AFEB deals with and will in the future.

4 Basically as our new knowledge of the human
5 genome grows, genetics and genetic techniques are
6 probably going to profoundly affect our future
7 diagnosis, care, and therapy within medicine and
8 within the military. Within the military, it is
9 probably going to have a lot of effects in terms
10 of operational applications.

11 As the human genome gets identified,
12 we are going to be able to identify more and more
13 screening tests that will assist in disease
14 surveillance as well as identify individuals that
15 are at higher or lower risk for disease due to
16 military unique exposures. So the Army office of
17 the Surgeon General actually chartered this
18 process action team about 18 months ago. It got
19 going about a year ago with Tri-Service input
20 plus Coast Guard and also the VA and the Public
21 Health Service has been involved.

22 The team was examining the
23 implications of the emerging genetic technologies
24 and we have been working on a report to make
25 recommendations on those effects for operational

1 medicine, clinical services, laboratory genetics,
2 research and development, and then, of course,
3 the ethics of all this new technology and how
4 that is going to effect.

5 The report has been drafted and is
6 presently undergoing revision. It should be
7 finalized by this summer and probably I hope the
8 board will get to see that when it comes out.
9 That is everything I had to talk about this
10 afternoon. If there are any questions, I will do
11 my best to answer them.

12 COLONEL O'DONNELL: Who is the Army
13 representative on that team?

14 COMMANDER ARDAY: There are several.
15 Lieutenant Colonel Wheaton, Victor Wheaton from
16 AFIP is actually the lead and has been doing this
17 as a civilian from AFIP, Ed Kane. I am trying to
18 think of -- there is another Army representative.

19 Major Doodevoir was supposed to be the resource
20 representative from OTSG, but he hasn't
21 participated in the last few months. I don't
22 know if he has kind of dropped out. Those are
23 three that come to mind. There is a fourth one,
24 and I can't think of his name at the moment.

25 Most of the R&D stuff has been from

1 the Air Force, as I recall, because they have got
2 the Medical Genetics Center down at Maxwell Air
3 Force Base, is that right, down in Alabama. So
4 they have got the only real -- the Air Force has
5 the biggest existing medical genetics capability.

6 I think the Army has one certified medical
7 geneticists and the Navy has one at the moment.

8 Of course, the Coast Guard doesn't have any. I
9 kind of fill in for that.

10 DR. ASCHER: How is the health care
11 for the HIV positives that are discharged
12 managed? What is the agency that provides it?
13 Is it private or CHAMPUS or active duty or VA or
14 what?

15 COMMANDER ARDAY: I think it is
16 primarily VA. Colonel Braden is shaking her
17 head. She knows it better than I do.

18 DR. ASCHER: But there is a small
19 number, as you've said, right?

20 COMMANDER ARDAY: Right. I mean
21 overall since we started HIV testing in 1988, we
22 have probably discharged fewer than 30 people.
23 So not a lot.

24 COLONEL TAKAFUJI: I would like to
25 make a comment. I am Colonel Takafuji. This

1 last project that you were talking about having
2 to do with the genetic screening and the
3 implications of molecular biology and the field
4 of medicine I think is a critical issue for us in
5 the Department of Defense and I think it needs to
6 be carefully worked and methodically worked
7 because the implications are far and wide.

8 I was mentioning to Dr. Gwaltney
9 earlier this afternoon, the military has always
10 been seen to be on the forefront of things having
11 to do with screening, testing, sociological
12 issues. Certainly, the HIV is a striking example
13 of that. Dr. Ascher is absolutely right that the
14 AFEB should be involved with all of the
15 implications that are coming out as a result of
16 policy and that regard. But also with the
17 technologies. We are going to have a striking
18 impact on everything that we do from accession
19 testing to retention to identifying people that
20 may be qualified or disqualified for certain
21 types of duties and responsibilities in the
22 military. I think that that should be done in a
23 very methodical way, but I am sensing that there
24 are some missing players in a process that is
25 taking place driven primarily by geneticists.

1 I don't know quite where it started
2 and I am not quite sure where it is going, but I
3 don't know who put together this process action
4 team, whether it was an AFIP initiated project or
5 where. Do you have any idea on that?

6 COMMANDER ARDAY: Lieutenant General
7 Nanoo.

8 COLONEL TAKAFUJI: And he put the
9 process action team without involvement of the
10 players that have implications?

11 COLONEL CIRONE: He established the
12 process action team, made a chair, and went out
13 and requested participants for it. Perhaps you
14 had some briefings by research and development
15 personnel to the process action team. I haven't
16 been to all the meetings, so I don't know.

17 DR. ASCHER: How many Armies are there
18 now. Let's see.

19 COLONEL FOGELMAN: I think maybe we
20 can continue this discussion off line.

21 DR. ASCHER: The hot genetics are in
22 breast cancer. You know you want to do MEP
23 screening for breast cancer genes?

24 DR. KULLER: Well, okay.

25 COLONEL FOGELMAN: Okay. Thank you

1 very much. That concludes our discussion for
2 today. If the board members and the PM officers
3 could stay for just a few minutes, I would really
4 appreciate it. I will see everyone tomorrow at
5 8:00.

6 (Whereupon, at 4:51 p.m. the meeting
7 was adjourned to reconvene the following day at
8 8:00 a.m.)